

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

COUNTY OF ROCKLAND, NEW YORK,

Plaintiff,

v.

PURDUE PHARMA, L.P.;
PURDUE PHARMA, INC.;
THE PURDUE FREDERICK COMPANY;
RICHARD SACKLER;
MALLINCKRODT PLC;
MALLINCKRODT LLC;
SPECGX LLC;
TEVA PHARMACEUTICALS INDUSTRIES,
LTD.;
TEVA PHARMACEUTICALS USA, INC.;
CEPHALON, INC.;
JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.;
ORTHO-MCNEIL-JANSSEN
PHARMACEUTICALS, INC. n/k/a JANSSEN
PHARMACEUTICALS, INC.;
JANSSEN PHARMACEUTICA, INC. n/k/a
JANSSEN PHARMACEUTICALS, INC.;
NORAMCO, INC.;
AMERISOURCEBERGEN DRUG
CORPORATION;
CARDINAL HEALTH, INC.;
CARDINAL HEALTH PHARMACY
SERVICES, LLC;
MCKESSON CORPORATION;
ROCHESTER DRUG COOPERATIVE, INC.;
CVS PHARMACY, INC.;
CVS HEALTH CORPORATION;
CAREMARKPCS HEALTH, L.L.C.
d/b/a CVS CAREMARK;
WALGREENS BOOTS ALLIANCE, INC.;
AND WALGREENS BOOTS
ALLIANCE, INC., AS SUCCESSOR IN
INTEREST TO RITE AID CORPORATION,

Defendants.

Case No. _____

JURY TRIAL DEMANDED

COMPLAINT

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COMPLAINT

Plaintiff County of Rockland, New York brings this Complaint against Defendants Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company, Inc., Richard Sackler, Mallinckrodt plc, Mallinckrodt LLC, SpecGx LLC, Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., Cephalon, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals Inc., Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc., Noramco, Inc. (“Manufacturer Defendants”), AmerisourceBergen Drug Corporation, Cardinal Health, Inc., Cardinal Health Pharmacy Services, LLC, and McKesson Corporation (“Distributor Defendants”), and CVS Pharmacy, Inc., CVS Health Corporation, CaremarkPCS Health, L.L.C. d/b/a CVS Caremark; Walgreens Boots Alliance, Inc.; and Walgreens Boots Alliance, Inc., as successor in interest to Rite Aid Corporation (“Retailer Defendants”) (collectively “Defendants”). Based upon personal knowledge, information, belief, and investigation of counsel, County of Rockland alleges:

INTRODUCTION

1. To say that the country is awash in opioids is a monumental understatement. The United States only accounts for roughly five percent of the world’s total population, but consumes approximately 80 percent of the world’s opioids, including 99 percent of the world’s hydrocodone. Even more staggering are the number of opioid-related deaths: each day, more than 90 people in the United States will die from an opioid overdose. The unprecedented rate of opioid overdose has actually caused death rates in the United States to rise again, reversing a 100-year decline in mortality statistics.

2. In New York, the opioid crisis has reached epidemic proportions. There were more 8,500,000 more opioid prescriptions than people in New York in 2017. Paramedics in the state

are increasingly spending time responding to overdoses and coroners' offices are running out of room to store bodies. New York State Department of Health data shows that 3,224 New Yorkers died from drug overdoses involving opioids in 2017, the highest number of such deaths recorded in state history.¹ That was a 545% percent increase from the approximately 500 overdose deaths recorded among New York residents in 1999.²

3. The opioid epidemic did not appear overnight. It is the result of a concerted effort among the Manufacturer Defendants, along with other opioid manufacturers, to mislead doctors and the public about the need for, and addictive nature of, opioid drugs. The Manufacturer Defendants spent years engaged in a fraudulent scheme to push their wares into a market of unsuspecting doctors and patients. When it became clear that entire regions of the country were being devastated by addiction to these drugs, the Manufacturer Defendants turned a blind eye to the problems and collected millions of dollars in ill-gotten profits.

4. The Manufacturer Defendants falsely and misleadingly: (a) downplayed the serious risk of addiction; (b) promoted the concept of "pseudoaddiction" and thus advocated that the signs of addiction should be treated with more opioids; (c) exaggerated the effectiveness of screening tools in preventing addiction; (d) claimed that opioid dependency and withdrawal are easily managed; (e) denied the risks of higher opioid dosages; and (f) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. The Manufacturer Defendants also falsely touted the benefits of long-term opioid use, including the purported ability of opioids to improve function and quality of life, even though there was no reliable scientific evidence to support the Manufacturer Defendants' claims.

¹ New York Opioid Summary. Available at: <https://www.drugabuse.gov/opioid-summaries-by-state/new-york-opioid-summary>

² *Id.*

5. The Manufacturer Defendants disseminated these common messages to reverse the popular and medical understanding of opioids. They disseminated these messages directly, through their sales representatives, and in speaker groups led by physicians that Defendants recruited for their support of Defendants' marketing messages.

6. The Manufacturer Defendants also worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors, known as "key opinion leaders" ("KOLs") and (b) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups"). The Manufacturer Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, medical conferences and seminars, and scientific articles. Working individually and collectively, and through these Front Groups and KOLs, Defendants persuaded doctors and patients that what they had long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue, and convinced them of quite the opposite, that the compassionate treatment of pain *required* opioids.

7. The Manufacturer Defendants knew that their misrepresentations of the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence. Indeed, the falsity of each Defendant's misrepresentations has been confirmed by the U.S. Food and Drug Administration ("FDA") and the Centers for Disease Control and Prevention ("CDC"), including by the CDC in its *Guideline for Prescribing Opioids for Chronic Pain*, issued in 2016 and approved by the FDA.

8. Opioid manufacturing and distributing companies systematically and repeatedly disregarded the health and safety of their customers and the public. Charged by law to monitor and

report dangerous behavior, they failed to do so in favor of maximizing corporate profits and increasing their market share.

9. The Distributor Defendants are major distributors of controlled substances. Not only the Manufacturer Defendants, but also the Distributor Defendants were aware of a growing epidemic from abuse, addiction, and diversion of the prescription opioids they supplied. The Manufacturer Defendants and the Distributor Defendants were aware of the quantities and frequency with which those drugs were distributed in Rockland County. However, both the Manufacturer Defendants and the Distributor Defendants persisted in failing to report suspicious sales as required by state and federal law. Their failure to follow the law significantly contributed to increasing abuse, addiction, and overdose rates in Rockland County.

10. The Distributor Defendants' violations have already led to fines elsewhere. McKesson Corporation, the largest prescription drug wholesaler company in the United States, agreed on January 17, 2017, to pay a \$150 million fine to the federal government for such misconduct.³ In December 2016, Cardinal Health, Inc. reached a \$34 million settlement with the federal government.⁴ One month later, Cardinal Health, Inc. reached a \$20 million settlement with the State of West Virginia.⁵ AmerisourceBergen Drug Corporation also recently agreed to pay West Virginia \$16 million for similar violations.⁶

³ 2017 Administrative Memorandum of Agreement (DOJ, DEA and McKesson). Available at: <https://www.justice.gov/opa/press-release/file/928476/download>.

⁴ Press Release, *United States Reaches \$34 Million Settlement With Cardinal Health For Civil Penalties Under The Controlled Substances Act*, DOJ, U.S. Attorney's Office – Middle District of Florida. Available at: <https://www.justice.gov/usao-mdfl/pr/united-states-reaches-34-million-settlement-cardinal-health-civil-penalties-under>.

⁵ Eric Eyre, *2 drug distributors to pay \$36M to settle WV painkiller lawsuits*, Charleston Gazette-Mail, January 9, 2017. Available at: <http://www.wvgazettemail.com/news-cops-and-courts/20170109/2-drug-distributors-to-pay-36m-to-settle-wv-painkiller-lawsuits>.

⁶ *Id.*

11. Defendants' scheme has met with tremendous success, if measured by profit. In 2010 alone, opioids generated \$11 billion in revenue for drug companies.⁷ Of that amount, \$3.1 billion went to Purdue for its OxyContin sales.⁸ Opioids are now among the most prescribed class of drugs, and the United States' opioid painkiller market is worth an estimated \$10 billion annually.⁹ According to *Fortune* magazine, the Distributor Defendants are each among the top 15 companies in the 2017 *Fortune* 500: McKesson, No. 5, with \$192 billion in total revenue; AmerisourceBergen, No. 11, with \$122 billion in total revenue; and Cardinal Health, No. 15, with \$122 billion in total revenue.¹⁰ Additionally, the Sackler family, which owns Purdue – a privately held company – was included on Forbes 2015 list of America's Richest Families, coming in at a stunning \$14 billion.¹¹

12. The rising numbers of persons addicted to opioids have led to increased health care costs and a dramatic increase in social problems, including drug abuse and diversion and the commission of criminal acts to obtain opioids throughout the United States, including Rockland County. Public health and safety throughout the United States, including Rockland County, has been significantly and negatively affected due to widespread inappropriate use of the drugs

⁷ Katherine Eban, *OxyContin: Purdue Pharma's painful medicine*, *Fortune.com*, Nov. 9, 2011. Available at: <http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/>.

⁸ *Id.*

⁹ Ariana Eun Jung Cha, *The drug industry's answer to opioid addiction: More pills*, *The Washington Post*, Oct. 16, 2016. Available at: https://www.washingtonpost.com/national/the-drug-industrys-answer-to-opioid-addiction-more-pills/2016/10/15/181a529c-8ae4-11e6-bff0-d53f592f176e_story.html?utm_term=.42e0328ca459.

¹⁰ Erika Fry, *As America's Opioid Crisis Spirals, Giant Drug Distributor McKesson Is Feeling the Pain*, *Fortune.com*, June 13, 2017. Available at: <http://fortune.com/2017/06/13/fortune-500-mckesson-opioid-epidemic/>.

¹¹ Alex Morrell, *The OxyContin Clan: The \$14 Billion Newcomer to Forbes 2015 List of Richest U.S. Families*, *Forbes*, July 1, 2015. Available at: <https://www.forbes.com/sites/alexmorrell/2015/07/01/the-oxycontin-clan-the-14-billion-newcomer-to-forbes-2015-list-of-richest-u-s-families/#4b11d5d375e0>.

manufactured and distributed by Defendants.

13. As a direct and foreseeable consequence of Defendants' wrongful conduct, Plaintiff incurred considerable expenses each year in efforts to combat the opioid epidemic created by Defendants' conduct. Plaintiff County of Rockland has incurred and continues to incur costs related to opioid addiction and abuse, including, but not limited to, health care costs, criminal justice and victimization costs, social costs, lost productivity, and lost revenue.

JURISDICTION AND VENUE

14. This Court has jurisdiction over this action under 28 U.S.C. § 1331 based on the federal claims asserted under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq.* ("RICO"). This Court has supplemental jurisdiction over Plaintiff's state-law claims under 28 U.S.C. § 1367 because those claims are so related to Plaintiff's federal claims that they form part of the same cause or controversy.

15. The Court has personal jurisdiction over Defendants because at all relevant times Defendants engaged in substantial business activities in the State of New York, purposefully directed their actions toward New York, consensually submitted to the jurisdiction of New York when obtaining a manufacturer or distributor license, and have the requisite minimum contacts with New York necessary to constitutionally permit the Court to exercise jurisdiction.

16. Venue is proper in this District under 28 U.S.C. § 1391 and 18 U.S.C. § 1965 because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacted affairs and conducted activity that gives rise to the claim of relief in this District. Moreover, Plaintiff County of Rockland is located in this District, and a substantial part of property that is the subject of this action is situated in this District.

PARTIES

I. Rockland County

17. Rockland County, New York is located within the Southern District of New York. According to U.S. Census Bureau statistics, it is estimated that Rockland County's total population was 328,868 in June 2018. Its county seat is New City.

18. The current County Executive of the County of Rockland is Ed Day. Rockland County is governed by a County Executive and District Legislature consisting of seventeen members.

19. County of Rockland has the authority under the laws of the State of New York to bring this lawsuit.

II. Manufacturer Defendants

A. Purdue and Richard Sackler

20. **Defendant Purdue Pharma L.P., is a** limited partnership organized under the laws of Delaware. Defendant Purdue Pharma Inc. is a New York corporation with its principal place of business in Stamford, Connecticut, and Defendant The Purdue Frederick Company, Inc. is a Delaware corporation with its principal place of business in Stamford, Connecticut. Defendants **Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company are referred to collectively as "Purdue."**

21. In New York and nationally, Purdue is engaged in the manufacture, promotion, and distribution of opioids, including: (a) OxyContin (OxyContin hydrochloride extended release), a

Schedule II opioid agonist¹² tablet first approved in 1995 and marketed by Purdue for the “management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.” OxyContin was indicated, or legally approved, for the “management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.”; (b) MS OxyContin (morphine sulfate extended release), a Schedule II opioid agonist tablet first approved in 1987 and indicated for the “management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.”

22. OxyContin is Purdue’s largest-selling opioid. Since 2009, Purdue’s national annual sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up approximately four-fold from 2006 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

23. Purdue transacts business in New York, targeting the New York market for its products, including the opioids at issue in this lawsuit. Purdue hires employees to service the New York market.

24. Defendant Richard Sackler became a member of the Purdue board in 1990 and became its co-chair in 2003, which he remained until he left the board in 2018. He was also Purdue’s head of research and development from at least 1990 through 1999, and its president from 1999 through 2003. He resides in New York, Florida, and Texas. He currently holds an active license to practice medicine issued by the New York State Education Department. He is a trustee of the Sackler School of Medicine, a director and the vice president of the Raymond and Beverly

¹² An opioid *agonist* is a drug that activates certain opioid receptors in the brain. By contrast, an *antagonist* relieves pain by blocking the receptor.

Sackler Foundation, Inc., all three of which are New York Not-for-Profit Corporations. In September 2017, through a trust he ultimately controls for the benefit of his children and grandchildren, and with proceeds from his interests in Purdue, he purchased a condominium on Manhattan's East Side for \$3.225 million.

B. Mallinckrodt

25. Defendant Mallinckrodt plc is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom and maintains a U.S. headquarters in St. Louis, Missouri. Defendant Mallinckrodt LLC is a Delaware limited liability company with its principal place of business in St. Louis, Missouri.

26. Defendant SpecGx LLC is a Delaware limited liability company with a principal place of business in Clayton, Missouri. SpecGx was formed on November 14, 2016 as a wholly owned subsidiary of Mallinckrodt LLC. Mallinckrodt plc, Mallinckrodt LLC, and SpecGx LLC are referred to collectively as "Mallinckrodt."

27. In New York and nationally, Mallinckrodt is engaged in the manufacture, promotion, and distribution of hydrocodone, Roxycodone, Oxycodone and hydromorphone among other drugs. Mallinckrodt transacts business in New York, targeting the New York market for its products, including the opioids at issue in this lawsuit. Mallinckrodt hires employees to service the New York market. For example, Mallinckrodt operates an opioids manufacturing facility in Hobart, New York.

C. Cephalon and Associated Companies

28. Defendant Teva Pharmaceutical Industries, Ltd. is an Israeli corporation with its principal place of business in Petah Tikva, Israel.

29. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of

business in Frazer, Pennsylvania.

30. Teva Pharmaceuticals Ltd. acquired Cephalon, Inc. in October 2011, and Cephalon Inc. became a wholly owned subsidiary of Teva Pharmaceuticals Ltd.

31. Defendant Teva Pharmaceuticals USA, Inc. is a Delaware corporation with its principal place of business in North Wales, Pennsylvania and is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd. in Pennsylvania.

32. Teva Pharmaceuticals Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to collectively as “Cephalon.”

33. In New York and nationally, Cephalon is engaged in the manufacture, promotion, and distribution of hydrocodone and oxycodone among other drugs. Cephalon transacts business in New York, targeting the New York market for its products, including the opioids at issue in this lawsuit. Cephalon also directs advertising and information materials to impact New York physicians and potential users of Cephalon products.

D. Janssen and Associated Companies

34. Defendant Johnson & Johnson is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

35. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Johnson & Johnson.

36. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which was formerly known as Janssen Pharmaceutica, Inc.

37. Defendant Noramco, Inc. is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of Johnson & Johnson until July 2016. Noramco,

Inc. is or had been part of Johnson & Johnson's opioid processing by making active pharmaceutical ingredients ("APIs") for opioid painkillers.

38. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

39. Janssen Pharmaceutica, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

40. Johnson & Johnson is the only company that owns over 10% of Janssen Pharmaceuticals stock. Johnson & Johnson controls the sale and development of Janssen Pharmaceuticals drugs and Janssen Pharmaceuticals profits inure to Johnson & Johnson's benefit.

41. Johnson & Johnson, Janssen Pharmaceuticals, Inc., Noramco, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc. are referred to collectively as "Janssen."

42. Janssen is or has been in the business of manufacturing, selling, promoting, and/or distributing brand name and generic opioids throughout the United States, including in New York.

III. Distributor Defendants

A. AmerisourceBergen

43. Defendant AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a Delaware corporation with its principal place of business located in Chesterbrook, Pennsylvania. AmerisourceBergen is the second largest pharmaceutical distributor in North America.

44. According to its 2016 Annual Report, AmerisourceBergen is "one of the largest global pharmaceutical sourcing and distribution services companies, helping both healthcare providers and pharmaceutical and biotech manufacturers improve patient access to products and

enhance patient care.”

B. Cardinal Health

45. Defendant Cardinal Health, Inc. is an Ohio Corporation with its principal place of business in Dublin, Ohio. Cardinal Health Pharmacy Services, LLC is a Delaware company with a principal office in Ohio. (collectively “Cardinal Health”). In 2016, Cardinal Health generated revenues of \$121.5 billion.

46. Cardinal Health is a global distributor of pharmaceutical drugs and medical products. It is one of the largest distributors of opioids in the United States. Additionally, in December 2013, Cardinal Health formed a ten-year agreement with CVS Caremark to form the largest generic drug sourcing operation in the United States. Cardinal Health has, at all relevant times, distributed opioids nationwide.

C. McKesson

47. Defendant McKesson Corporation (“McKesson”) is a Delaware Corporation with its principal place of business located in San Francisco, California.

48. McKesson is the largest pharmaceutical distributor in North America. McKesson delivers approximately one-third of all pharmaceuticals used in North America.

49. For fiscal year ended March 31, 2017, McKesson generated revenues of \$198.5 billion.

50. In its 2017 Annual Report, McKesson states that it “partner[s] with pharmaceutical manufacturers, providers, pharmacies, governments and other organizations in healthcare to help provide the right medicines, medical products and healthcare services to the right patients at the right time, safely and cost-effectively.”

51. According to the 2017 Annual Report, McKesson “pharmaceutical distribution

business operates and serves thousands of customer locations through a network of 27 distribution centers, as well as a primary redistribution center, two strategic redistribution centers and two repackaging facilities, serving all 50 states and Puerto Rico.”

52. McKesson is the largest pharmaceutical distributor in the United States.

53. McKesson has more than 40,000 customers nationally.

54. Collectively, McKesson, AmerisourceBergen, and Cardinal Health account for 85 percent of the drug shipments in the United States. These companies together collect about \$400 billion in annual revenue.

D. Rochester Drug

55. Defendant Rochester Drug Cooperative, Inc. (“Rochester Drug”) is a New York corporation. Its principal place of business is Rochester, New York.

56. Rochester Drug distributed prescription opioids throughout the United States, including the State of New York and Rockland County.

57. Rochester Drug is among the ten largest wholesalers in the United States, with an estimated revenue of \$2 billion.

IV. Retailer Defendants

A. Walgreens/Rite-Aid

58. Walgreens Boots Alliance, Inc. and Walgreen Co. are Delaware corporations with its principal headquarters and principal place of business located in Deerfield, Illinois (“Walgreens”). Walgreens is successor in interest to “Rite Aid.” Rite Aid Corporation is a Delaware corporation with its principal headquarters and principal place of business located in Camp Hill, Pennsylvania. Rite Aid Headquarters Corp. is a Delaware corporation with a principal place of business in Camp Hill, Pennsylvania. Plaintiffs refer to these entities and the associated

retail pharmacy stores collectively as “Rite Aid” herein.

B. CVS Health

59. CVS Health Corporation is a Delaware corporation with its principal place of business in Woonsocket, Rhode Island. CVS Pharmacy, Inc. is a Rhode Island corporation with its headquarters and principal place of business in Woonsocket, Rhode Island. CaremarkPCS Health, L.L.C. d/b/a CVS Caremark is a Delaware corporation with a principal place of business in Woonsocket, Rhode Island. Plaintiffs refer to these entities and the associated retail pharmacy stores collectively as “CVS” herein.

60. Rite Aid and CVS (collectively, the “Retailer Defendants”) are engaged in the business of retail selling of opioids. They are collectively referred to herein as the “Retailer Defendants.” Upon information and belief, the Retailer Defendants knowingly filled suspicious orders and improper prescriptions, and also utilized a perverse incentive system for their employees that incentivized pharmacists to fill suspicious orders.

61. The Retailer Defendants operate various retail pharmacies in Rockland County, New York, conducted business in Rockland County, New York, and purposely directed their actions towards New York. They also hold New York licenses to dispense prescription drugs, including the opioids at issue in this lawsuit, within New York. The Retailer Defendants dispensed many of the opioids at issue in this lawsuit, including opioids produced the Manufacturer Defendants and distributed by the Distributor Defendants. The Retailer Defendants’ activities within the Counties and directed at the Counties are continuous and systematic, giving rise to the claims asserted herein.

FACTUAL ALLEGATIONS

I. Opioids have never been proven appropriate for the treatment of chronic pain and other non-acute medical problems

62. To understand the central role the Manufacturer Defendants played in the creation of the United States', New York's, and Rockland County's opioid crisis, one must understand that their marketing of opioids for chronic pain and other non-acute ailments, which created the current generation of opioid addicts, was based on fraud and was entirely contrary to science. The scientific consensus that opioids are dangerous, highly addictive, and inappropriate for chronic pain – as opposed to cancer pain and pain associated with surgery and acute injuries – existed in the mid-1990s and has never been challenged in any meaningful way with new, valid scientific evidence.

63. The National Safety Council, a not for profit organization chartered by Congress to improve public health, has published a summary of research titled “Evidence for the Efficacy of Pain Medications.”¹³ The National Safety Council report concludes that “[d]espite the widespread use of opioid medications to treat chronic pain, there is no significant evidence to support this practice.”¹⁴

64. Multiple researchers have found that “no evidence exists to support long term use – longer than four months – of opioids to treat chronic pain.”¹⁵

65. A 2013 review of existing literature by Dr. Igor Kissin of the Department of Anesthesiology, Perioperative, and Pain Medicine at Brigham and Women's Hospital, Harvard

¹³ Donald Teater, Nat'l Safety Counsel, *Evidence for the Efficacy of Pain Medications*, 3 (2014) [hereinafter *Evidence for Efficacy*].

¹⁴ *Id.* at 6 (emphasis added).

¹⁵ *Id.* (citing multiple publications).

Medical School, concluded that “[n]ot a single randomized controlled trial with opioid treatment lasting [greater than] 3 months was found.”¹⁶

66. The same review found that “[a]ll studies with a duration of opioid treatment [greater than or equal to] 6 months were conducted without a proper control group.”¹⁷

67. Dr. Kissin further concluded that “[t]here is no strong evidence-based foundation for the conclusion that long-term opioid treatment of chronic malignant pain is effective.”¹⁸

II. Opioids carry a high risk of addiction, serious medical problems, and death

68. Opioids have severe side effects, including: gastrointestinal bleeding, impaired recovery from injury or surgery, cognitive impairment, respiratory depression, endocrine abnormalities, hyperalgesia (increased sensitivity to pain), increased risk of fractures and hospitalization for the elderly, addiction, and death.¹⁹

69. Research based on actual patient interviews has found that, **among patients who received four or more prescriptions in the prior year, 35% met the criteria for a lifetime opioid dependence and 25.8% met the criterial for current opioid dependence.**²⁰

70. Dr. Wilson M. Compton, the Director and Deputy Director of the National Institute of Drug Abuse at the National Institute of Health, respectively, co-authored a 2006 study that concluded: “[t]hough the use of opioid analgesics for the treatment of acute pain appears to be

¹⁶ Igor Kissin, *Long-term Opioid Treatment of Chronic Nonmalignant Pain: Unproven Efficacy and Neglected Safety?*, 2013:6 J. Pain Research 513, 513 (2013), available at <https://www.dovepress.com/long-term-opioid-treatment-of-chronic-nonmalignant-painnbspunproven-ef-peer-reviewed-article-JPR>.

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ Donald Teater, Nat’l Safety Council, *The Psychological and Physical Side Effects of Pain Medications*, 2-6 (2014) [hereinafter *Side Effects*] (summarizing side effect data).

²⁰ Joseph A. Boscarino, *Opioid-Use Disorder Among Patients on Long-Term Opioid TherapyI*, 2015:6 Substance Abuse and Rehabilitation 87, 87-89 (2015), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4548725/>.

generally benign, **long-term administration of opioids has been associated with clinically meaningful rates of abuse or addiction.**”²¹

71. Consistent with this finding, a 2011 review of medical and pharmacy claims records revealed that two-thirds of patients who took opioids daily for ninety days were still taking opioids five years later.²²

72. Researchers evaluating opioids for treatment following lumbar disc herniation likewise found that giving such patients opioids had no effect on treatment outcome, but significantly increased their risk for long term opioid addiction.²³

73. Dr. Mitchell H. Katz, current director of the Los Angeles County Health Agency, has described how patients with nonmalignant conditions can end up as drug addicts because of the prescribing of opioids:

A certain number of patients get better with NSAIDs [non-steroidal anti-inflammatory drugs, like Tylenol].... For those still complaining of pain, you next prescribe a short-acting opioid with a relatively low potency, such as acetaminophen with codeine. ... You tell them about the adverse effects of opioids and encourage them to use the lowest dose necessary. Not infrequently, at the next visit they tell you that the medicine works but that they are taking the pills more frequently than directed. At this point, you worry about liver damage from the acetaminophen and switch to a higher potency, longer acting agent. The patient returns for follow-up visits and tells you that the pills work but that they sometimes take an extra pill and could you please increase the number so they “don’t run out before the next visit.” Before you know it, the patient is on a high dose of an opioid, and you are unsure whether you have actually

²¹ Wilson M. Compton et al., *Major Increases in Opioid Analgesic Abuse in the United States: Concerns and Strategies*, 81 Nat’l Inst. on Drug Abuse 103, 103-07 (2006).

²² Bradley C. Martin et al., *Long-term Chronic Opioid Therapy Discontinuation Rates from the TROUP Study*, 26(12) J. Gen. Intern. Med. 1450, 1450-57 (2011).

²³ *Evidence for Efficacy at 5* (citing Radcliff et al., *Does Opioid Pain Medication Use Affect the Outcome of Patients with Lumbar Disk Herniation?*, 38(14) The Spine J. E849, E849-60 (2013)).

helped them. **What you know is you have committed yourself to endless negotiations about increasing doses, lost pill bottles, calls from emergency departments, worries that your patient is selling the drugs, and the possibility that one day, your patient will take too many pills, perhaps with alcohol, and overdose.**²⁴

III. The origins of the current opioid epidemic can be traced back to the Manufacturer Defendants’ decades-long fraudulent marketing campaign

74. The United States’ and New York’s opioid crisis is no accident: it is the result of a conspiracy between the Manufacturer Defendants and other opioid manufacturers to fraudulently convince physicians that opioids carried a low risk of addiction and were therefore appropriate for non-acute problems like chronic pain.

75. The Manufacturer Defendants aggressively marketed and falsely promoted liberal opioid prescribing as presenting little to no risk of addiction, even when used long term for chronic pain. The Manufacturer Defendants infiltrated academic medicine and regulatory agencies to convince doctors that treating chronic pain with long-term opioid use was evidence-based medicine when, in fact, it was not. Huge profits resulted from these efforts, as did the present, addiction, abuse, diversion, and overdose crisis.

A. The Manufacturer Defendants use “unbranded” marketing to evade laws and regulations

76. Drug companies’ promotional activity can be unbranded or branded. Unbranded marketing refers not to a specific drug, but more generally to a disease state or treatment. By using unbranded communications, drug companies can evade the extensive regulatory framework governing branded communications because unbranded advertising isn’t regulated by the FDA.

77. The federal Food, Drug, and Cosmetic Act (“FDCA”) prohibits the sale in interstate

²⁴ Mitchell H. Katz, *Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith*, 170(16) Arch Intern. Med. 1422, 1422-24 (2010).

commerce of drugs that are “misbranded.” A drug is “misbranded” if it lacks “adequate directions for use” or if the label is false or misleading “in any particular.”

78. The Manufacturer Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements through unregulated, unbranded marketing materials that generally promoted opioid use but did not name a specific opioid while doing so. Through these unbranded materials, the Manufacturer Defendants presented information and instructions concerning opioids generally that were false and misleading.

79. By acting through third parties, the Manufacturer Defendants could give the false appearance that their messages reflected the views of independent third parties. Later, the Manufacturer Defendants cited to these sources as “independent” corroboration of their own statements. Further, as one physician adviser to the Manufacturer Defendants noted, third-party documents had not only greater credibility, but also broader distribution, as doctors did not “push back” at having materials, for example, from the non-profit American Pain Foundation (“APF”) on display in their offices, as they would with drug company materials.

80. As part of their marketing scheme, the Manufacturer Defendants spread and validated their deceptive messages through the following unbranded materials: (i) so-called “key opinion leaders” (i.e., physicians who influence their peers’ medical practice, including but not limited to prescribing behavior) (“KOLs”), who wrote favorable journal articles and delivered supportive Continuing Medical Education (“CME”) programs; (ii) treatment guidelines; and (iii) unbranded patient education materials disseminated through groups purporting to be patient-advocacy and professional organizations (“Front Groups”), which exercised their influence both directly and indirectly through Defendant-controlled KOLs who served in leadership roles in these organizations.

81. The Manufacturer Defendants took an active role in guiding, reviewing, and approving many of the misleading statements issued by third parties, ensuring that the Manufacturer Defendants were consistently in control of their content. By funding, directing, editing, and distributing these materials, the Manufacturer Defendants exercised control over their deceptive messages and acted in concert with these third parties fraudulently to promote the use of opioids for the treatment of chronic pain.

82. The unbranded marketing materials that the Manufacturer Defendants assisted in creating and distributing did not disclose the risks of addiction, abuse, misuse, and overdose, and affirmatively denied or minimized those risks.

B. The Manufacturer Defendants paid so-called KOLs and sponsored speakers' bureaus to disseminate false and misleading messaging

83. The Manufacturer Defendants cultivated a select circle of doctors chosen and sponsored by the Manufacturer Defendants solely because they favored the aggressive treatment of chronic pain with opioids. Pro-opioid doctors have been at the hub of the Manufacturer Defendants' promotional efforts, presenting the appearance of unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain. These pro-opioid doctors have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of opioid therapy for chronic pain. They have served on committees that developed treatment guidelines that strongly encouraged the use of opioids to treat chronic pain and on the boards of purportedly independent pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. The Manufacturer Defendants were able to exert control of each of these modalities through their KOLs.

84. In return for their pro-opioid advocacy, the Manufacturer Defendants' KOLs received money, prestige, recognition, research funding, and avenues to publish.

85. The payments to KOLs all too frequently come in the form of consulting and speaking fees. The total payments from the Manufacturer Defendants to doctors related to opioids doubled from 2014 to 2015. Moreover, according to experts, research shows that even small amounts of money can have large effects on doctors' prescribing practices.²⁵

86. The use of speakers' bureaus has led to substantial ethical concerns within the medical field. According to a 2013 publication by the Institute on Medicine as a Profession ("IMAP"), speakers' bureaus are ethically compromised because they often present information as objective when it is heavily biased toward the interests of the industry sponsor.²⁶ As the IMAP publication explains: "Speakers' bureaus may lead to the dissemination of false or biased information. Exposure to industry-sponsored speaking events is associated with decreased quality of prescribing. Additionally, the compensation provided for these engagements may influence the attitudes or judgment of the presenter."²⁷

87. The Manufacturer Defendants cited and promoted their KOLs and studies or articles by their KOLs to broaden the chronic opioid therapy market. By contrast, the Manufacturer Defendants did not support, acknowledge, or disseminate the publications of doctors critical of using chronic opioid therapy.

88. The Manufacturer Defendants carefully vetted their KOLs to ensure that they were likely to remain on-message and supportive of their agenda. Manufacturer Defendants also kept close tabs on the content of the materials published by these KOLs.

²⁵ Joe Lawlor, *Even amid crisis, opioid makers plied doctors with perks*, Portland Press Herald (Dec. 25, 2016). Available at: <http://www.pressherald.com/2016/12/25/even-amid-crisis-opioid-makers-plied-doctors-with-perks/>.

²⁶ IMAP, *Speakers' Bureaus: Best Practices for Academic Medical Centers* (Oct. 10, 2013). Available at: http://imapny.org/wpcontent/themes/imapny/File%20Library/Best%20Practice%20toolkits/Best-Practices_Speakers--bureaus.pdf.

²⁷ *Id.*

89. In their promotion of using opioids to treat chronic pain, the Manufacturer Defendants' KOLs knew that their statements were false and misleading, or they recklessly disregarded the truth, but they continued to publish their misstatements to benefit themselves and Manufacturer Defendants.

C. The Manufacturer Defendants funded Front Groups that published and disseminated false and misleading marketing materials

90. The Manufacturer Defendants sponsored purportedly neutral medical boards and foundations that educated doctors and set guidelines for the use of opioids in medical treatment in order to promote the liberal prescribing of opioids for chronic pain. The following organizations, funded by the Manufacturer Defendants, advised doctors that liberal prescribing of opioids was both safe and effective. In truth, it was neither.

91. **Federation of State Medical Boards:** The Federation of State Medical Boards ("FSMB") is a national organization that functions as a trade group representing the 70 medical and osteopathic boards in the United States. The FSMB often develops guidelines that serve as the basis for model policies with the stated goal of improving medical practice. Defendants Purdue and Cephalon have provided substantial funding to the FSMB. Among its members are the Michigan Board of Medicine and the Michigan Board of Osteopathic Medicine and Surgery.

92. In 2007, the FSMB printed and distributed a physician's guide on the use of opioids to treat chronic pain titled "Responsible Opioid Prescribing" by Dr. Scott M. Fishman ("Fishman"). After the guide (in the form of a book, still available for sale on Amazon) was adopted as a model policy, the FSMB reportedly asked Purdue for \$100,000 to help pay for printing and distribution. Ultimately, the guide was disseminated by the FSMB to **700,000** practicing doctors.

93. The guide's clear purpose is to focus prescribers on the purported under-treatment

of pain and falsely assure them that opioid therapy is an appropriate treatment for chronic, non-cancer pain:

- Pain management is integral to good medical practice and for all patients;
- *Opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins;*
- *Patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient.*

Four key factors contribute to the ongoing problem of under-treated pain: (1)

Lack of knowledge of medical standards, current research, and clinical guidelines for appropriate pain treatment; (2) The perception that prescribing adequate amounts of opioids will result in unnecessary scrutiny by regulatory authorities; (3) *Misunderstanding of addiction and dependence*; and (4) Lack of understanding of regulatory policies and processes.²⁸

94. While it acknowledges the risk of “abuse and diversion” (with little attention to addiction), the guide purports to offer “professional guidelines” that will “easily and efficiently” allow physicians to manage that risk and “minimize the potential for [such] abuse.”²⁹ Indeed, it states that even for those patients assessed to have risk of substance abuse, “it does not mean that opioid use will become problematic or that opioids are contraindicated,” just that physicians should use additional care in prescribing.

²⁸ Scott M. Fishman, *Responsible Opioid Prescribing: A Physician’s Guide* 8-9 (Waterford Life Sciences 2007).

²⁹ *Id.* at 9.

95. The guide further warns physicians to “[b]e aware of the distinction between pseudoaddiction and addiction” and teaches that behaviors such as “[r]equesting [drugs] by name,” “[d]emanding or manipulative behavior,” “[o]btaining opioid drugs from more than one physician” and “[h]oarding opioids,” which are, in fact, signs of genuine addiction, are all really just signs of “pseudoaddiction.”³⁰ It defines “Physical Dependence” as an acceptable result of opioid therapy not to be equated with addiction and states that while “[i]t may be tempting to assume that patients with chronic pain and a history of recreational drug use who are not adherent to a treatment regimen are abusing medications,” there could be other acceptable reasons for non-adherence.³¹ The guide, sponsored by the Manufacturer Defendants and their pain foundations, became the seminal authority on opioid prescribing for the medical profession and dramatically overstated the safety and efficacy of opioids and understated the risk of opioid addiction.

96. In 2012, Fishman updated the guide and continued emphasizing the “catastrophic” “under-treatment” of pain and the “crisis” such under-treatment created:

Given the magnitude of the problems related to opioid analgesics, it can be tempting to resort to draconian solutions: clinicians may simply stop prescribing opioids, or legislation intended to improve pharmacovigilance may inadvertently curtail patient access to care. As we work to reduce diversion and misuse of prescription opioids, ***it’s critical to remember that the problem of unrelieved pain remains as urgent as ever.***³²

97. The updated guide still assures that “[o]pioid therapy to relieve pain and improve ***function is legitimate medical practice for acute and chronic pain of both cancer and noncancer***

³⁰ *Id.* at 62.

³¹ *Id.*

³² Scott M. Fishman, *Responsible Opioid Prescribing: A Guide for Michigan Clinicians*, 10-11 (Waterford Life Sciences 2012).

origins.”³³

98. In another guide by Fishman, he continues to downplay the risk of addiction: “*I believe clinicians must be very careful with the label ‘addict.’ I draw a distinction between a ‘chemical coper’ and an addict.*”³⁴ The guide also continues to present symptoms of addiction as symptoms of “pseudoaddiction.”

99. The heightened focus on the under-treatment of pain was a concept designed by Big Pharma to sell opioids. *The FSMB actually issued a report calling on medical boards to punish doctors for inadequately treating pain.*³⁵ Among the drafters of this policy was Dr. J. David Haddox (“Haddox”), who coined the term “pseudoaddiction,” which wholly lacked scientific evidence but quickly became a common way for the Manufacturer Defendants and their allies to promote the use of opioids even to patients displaying addiction symptoms. Haddox later became a Purdue Vice President.

100. In 2012 and again in 2017, the guides and the sources of their funding became the subject of a Senate investigation.

101. On June 8, 2012, the FSMB submitted a letter to the Senate Finance Committee concerning its investigation into the abuse and misuse of opioids.³⁶ While the letter acknowledged the escalation of drug abuse and related deaths resulting from prescription painkillers, the FSMB continued to focus on the “serious and related problem” that “[m]illions of Americans suffer from

³³ *Id.* at 11.

³⁴ Scott M. Fishman, *Listening to Pain: A Physician’s Guide to Improving Pain Management Through Better Communication* 45 (Oxford University Press 2012).

³⁵ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012, at A1. Available at: <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>.

³⁶ June 8, 2012 Letter from Federation of State Medical Boards to U.S. Senators Max Baucus and Charles Grassley.

debilitating pain – a condition that, for some, can be relieved through the use of opioids.” Among other things, the letter stated, “Studies have concluded that both acute pain and chronic pain are often under-treated in the United States, creating serious repercussions that include the loss of productivity and quality of life.” The letter cited no such studies. The letter also confirmed that the FSMB’s “Responsible Opioid Prescribing: A Physician’s Guide” has been distributed in each of the 50 states and the District of Columbia.

102. In addition, the FSMB letter disclosed payments the FSMB received from organizations that develop, manufacture, produce, market or promote the use of opioid-based drugs from 1997 through the present. Included in the payments received are the following payments: Defendant Purdue paid the FSMB a total of \$822,400.06 from 2001 to 2008; Defendant Cephalon paid the FSMB a total of \$180,000.00 from 2007 to 2008 and 2011; and Defendant Mallinckrodt paid the FSMB \$100,000.00 in 2011.

103. The letter also disclosed payments of \$50,000 by Purdue to directly fund the production of “Responsible Opioid Prescribing” and disclosed that 42,366 copies of “Responsible Opioid Prescribing” were distributed in Michigan alone.

104. **The Joint Commission:** The Joint Commission is an organization that establishes standards for treatment and accredits healthcare organizations in the United States. The Manufacturer Defendants, including Purdue, contributed misleading and groundless teaching materials and videos to the Joint Commission, which emphasized what Big Pharma coined the “under-treatment of pain,” referenced pain as the “fifth vital sign” (the first and only unmeasurable/subjective vital sign) that must be monitored and treated, and encouraged the use of prescription opioids for chronic pain while minimizing the danger of addiction. It also called doctors’ concerns about addiction “inaccurate and exaggerated.”

105. In 2000, the Joint Commission printed a book for purchase by doctors as part of required continuing education seminars that cited studies claiming “*there is no evidence that addiction is a significant issue when persons are given opioids for pain control.*” The book was sponsored by Defendant Purdue.

106. In 2001, the Joint Commission and the National Pharmaceutical Council – founded in 1953 and currently supported by the nation’s major research-based companies, including Johnson & Johnson, Purdue, and Cephalon, among others – collaborated to issue a 101-page monograph titled “Pain: Current understanding of assessment, management, and treatments.” The monograph states falsely that beliefs about opioids being addictive are “erroneous”:

Societal issues that contribute to the undertreatment of pain include drug abuse programs and erroneous beliefs about tolerance, physical dependence, and addiction (see I.E.5). For example, some clinicians incorrectly assume that exposure to an addictive drug usually results in addiction.

b. Etiology, issues, and concerns

Many medications produce tolerance and physical dependence, and some (e.g., opioids, sedatives, stimulants, anxiolytics, some muscle relaxants) may cause addiction in vulnerable individuals. Most experts agree that *patients who undergo prolonged opioid therapy usually develop physical dependence but do not develop addictive disorders. In general, patients in pain do not become addicted to opioids. Although the actual risk of addiction is unknown, it is thought to be quite low.* A recent study of opioid analgesic use revealed “low and stable” abuse of opioids between 1990 and 1996 despite significant increases in opioids prescribed. . . .

Fear of causing addiction (i.e., iatrogenic addiction), particularly with opioid use, is a major barrier to appropriate pain management. This fear sometimes reflects a lack of understanding of the risk of addiction with therapeutic drug use. Although studies suggest that the risk of iatrogenic addiction is quite low (e.g., Perry and Heidrich, Zenz et al.), surveys indicate that clinicians often

*overestimate this risk.*³⁷

107. The Manufacturer Defendants' infiltration and influence over the Joint Commission's standards and literature exerted overwhelming pressure on doctors to treat and eliminate pain. As more and more doctors migrated from private practice to integrated healthcare systems in the 2000s, treatment options were dictated by, among other things, the Joint Commission's guidelines.³⁸ Consistent with the guidelines, doctors who left pain untreated were viewed as demonstrating poor clinical skills and/or being morally compromised.³⁹

108. **American Pain Foundation**: The American Pain Foundation ("APF"), headquartered in Baltimore, Maryland, described itself as the nation's largest organization for pain patients. While APF held itself out as an independent patient advocacy organization, in reality it received 90% of its funding in 2010 from the drug and medical-device industry, including from defendants Purdue, Janssen and Cephalon. It received more than \$10 million in funding from opioid manufacturers from 2007 to 2012, when it shut down days after the U.S. Senate Committee on Finance ("Senate Finance Committee") launched an investigation of APF's promotion of prescription opioids.

109. The APF's guides for patients, journalists and policymakers trivialized the risk of addiction and greatly exaggerated the benefits associated with opioid painkillers.

110. For example, in 2001, APF published "Treatment Options: A Guide for People Living with Pain." The guide, which was produced due to support from companies including Defendants Cephalon and Purdue, misrepresented the risks associated with opioid use. Among

³⁷ *Pain: Current Understanding of Assessment, Management, and Treatments* 16-17 (Dec. 2001). Available at: <http://www.npcnow.org/system/files/research/download/Pain-Current-Understanding-of-Assessment-Management-and-Treatments.pdf>.

³⁸ Anna Lembke, *Drug Dealer, MD: How Doctors Were Duped, Patients Got Hooked, and Why It's So Hard to Stop*, at 119 (Johns Hopkins University Press 2016).

³⁹ *Id.* at 42.

other things, the guide:

- lamented that opioids were sometimes called narcotics because “[c]alling *opioid analgesics ‘narcotics’ reinforces myths and misunderstandings* as it places emphasis on their potential abuse rather than on the importance of their use as pain medicines”;
- stated that “[o]pioids are an essential option for treating *moderate* to severe pain associated with surgery or trauma;” and
- opined that “[r]estricting access to the most effective medications for treating pain [opioids] is not the solution to drug abuse or addiction.”

111. The guide included blurbs from Dr. Russell Portenoy (“Portenoy”), who is quoted as saying “[t]his is a very good resource for the pain patient,” and Fishman, who is quoted as saying, “[w]hat a great job! Finally, a pill consumer resource created for patients with pain. A ‘must have’ for every physician’s waiting room.”

112. In 2003, APF published a newsletter titled “Best of . . . The Pain Community News” that purported to clarify any confusion over addiction and opioids and emphasized the “tragic consequence of leaving many people with severe pain under-treated because they – or their doctors – fear that opioids will cause addiction.”

113. In 2009, opioid manufacturers APF’s publication and distribution of “Exit Wounds: A Survival Guide to Pain Management for Returning Veterans & Their Families” (“Exit Wounds”), a book described as “the inspirational story of how one courageous veteran, with the aid of his family, recovered and thrived despite near death, traumatic brain injury, and the loss of a limb.” It also purported to “offer[] veterans and their families comprehensive and authoritative information on . . . treatment options, and strategies for self-advocating for optimal pain care and

medical resources inside and outside the VA system.”

114. Among other false statements, Exit Wounds reported: “Long experience with opioids shows that *people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications.*” APF thus distributed false information with the purpose of providing veterans false information they could use to “self-advocat[e]” for opioids while omitting a discussion of the risks associated with opioid use.

115. The APF also developed the National Initiative on Pain Control (“NIPC”), which ran a facially unaffiliated website called www.painknowledge.org. NIPC promoted itself as an education initiative and promoted its expert leadership team, including purported experts in the pain management field. The website painknowledge.org promised that, on opioids, “your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse.” Elsewhere, the website touted improved quality of life (as well as “improved function”) as benefits of opioid therapy. In a brochure available on painknowledge.org titled “Pain: Opioid Facts,” the NIPC misled that “people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted” and even refused to rule out the use of opioid pain relievers for patients who have a history of addiction to opioids.

116. In or around 2011, the APF published the “Policymaker’s Guide,” sponsored by Purdue, which dispelled the notion that “strong pain medication leads to addiction” by characterizing it as a “*common misconception*[.]”:

Many people living with pain, and even some health care practitioners, falsely believe that opioid pain medicines are universally addictive. As with any medication, there are risks, but these risks can be managed when these medicines are properly

prescribed and taken as directed.⁴⁰

117. The guide describes “pain in America” as “an evolving public health crisis” and characterizes concerns about opioid addiction as misconceptions: “Unfortunately, too many Americans are not getting the pain care they need and deserve. Some common reasons for difficulty in obtaining adequate care include: . . . *Misconceptions about opioid addiction.*”⁴¹ It even characterizes as a “*myth*” that “[c]hildren can easily become addicted to pain medications.”⁴² The guide further asserts, falsely, that “multiple clinical studies” have shown that opioids are effective in improving daily function, psychological health and health-related quality of life for chronic pain patients, which was not the case.

118. In December 2011, the *Washington Post* reported on ProPublica’s investigation of the APF, which detailed APF’s close ties to drug makers:

[T]he pills continue to have an influential champion in the American Pain Foundation, which describes itself as the nation’s largest advocacy group for pain patients. Its message: The risk of addiction is overblown, and the drugs are underused.

What the nonprofit organization doesn’t highlight is the money behind that message.

The foundation collected nearly 90 percent of its \$5 million in funding last year from the drug and medical-device industry – and closely mirrors its positions, an examination by ProPublica found.⁴³

⁴⁰ *A Policymaker’s Guide to Understanding Pain & Its Management*, American Pain Foundation, at 5. Available at: <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last visited Jan. 2, 2018).

⁴¹ *Id.* at 6.

⁴² *Id.* at 40.

⁴³ Charles Ornstein & Tracy Weber, *Patient advocacy group funded by success of painkiller drugs, probe finds*, Wash. Post (Dec. 23, 2011). Available at: https://www.washingtonpost.com/national/health-science/patient-advocacy-group-funded-by-success-of-painkiller-drugs-probe-finds/2011/12/20/gIQAgvczDP_story.html?utm_term=.b0c95f6870f4.

119. American Academy of Pain Medicine and American Pain Society: The Manufacturer Defendants, including at least Janssen and Purdue, have contributed funding to the American Academy of Pain Medicine (“AAPM”) and the American Pain Society (“APS”) for decades.

120. In 1997, the AAPM issued a “consensus” statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The chairman of the committee that issued the statement, Haddox, was, at the time, a paid speaker for Purdue. Haddox was later hired as Purdue’s vice president for health policy. The consensus statement, which also formed the foundation of the 1998 guidelines, was published on the AAPM’s website. AAPM’s corporate council includes Purdue, Depomed, Cephalon and other pharmaceutical companies. AAPM’s past presidents include Haddox (1998), Fishman (2005), Dr. Perry G. Fine (“Fine”) (2011) and Lynn R. Webster (“Webster”) (2013), all of whose connections to the opioid manufacturers are well-documented.

121. At or about the same time, the APS introduced the “pain as the 5th vital sign” campaign, followed soon thereafter by the U.S. Department of Veterans Affairs adopting that campaign as part of their national pain management strategy.

122. AAPM and APS issued guidelines in 2009 (“2009 Guidelines”) that continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines received funding from defendants Janssen, Cephalon, or Purdue.

123. The 2009 Guidelines falsely promoted opioids as safe and effective for treating chronic pain and concluded that the risk of addiction was manageable for patients regardless of

past abuse histories.⁴⁴ The 2009 Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians but also the body of scientific evidence on opioids; they were reprinted in the journal *Pain*, have been cited hundreds of times in academic literature and remain available online. The Manufacturer Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions.

IV. The Manufacturer Defendants' Specific Unlawful Conduct

124. The Manufacturer Defendants, through their own marketing efforts and publications and through their sponsorship and control of patient advocacy and medical societies and projects, caused deceptive materials and information to be placed into the marketplace, including to prescribers, patients, and payors in Rockland County. These promotional messages were intended to and encouraged patients to ask for, doctors to prescribe, and payors to pay for chronic opioid therapy.

125. Doctors are the gatekeepers for all prescription drugs so, not surprisingly, the Manufacturer Defendants focused the bulk of their marketing efforts, and their multi-million dollar budgets, on the professional medical community. Particularly because of barriers to prescribing opioids, which are regulated as controlled substances, the Manufacturer Defendants knew doctors would not treat patients with common chronic pain complaints with opioids unless doctors were persuaded that opioids had real benefits and minimal risks. Accordingly, the Manufacturer Defendants did not disclose to prescribers, patients or the public that evidence to support their promotional claims was inconclusive, non-existent or unavailable. Rather, each Manufacturer Defendant disseminated misleading and unsupported messages that caused the target audience to

⁴⁴ Roger Chou, *et al.*, *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10(2) J. Pain 113 (Feb. 2009). Available at: [http://www.jpain.org/article/S1526-5900\(08\)00831-6/pdf](http://www.jpain.org/article/S1526-5900(08)00831-6/pdf).

believe those messages were corroborated by scientific evidence. As a result, Rockland County doctors prescribed opioids long-term to treat chronic pain – something that most never would have considered prior to the Manufacturer Defendants’ campaign.

126. Drug company marketing materially impacts doctors’ prescribing behavior.⁴⁵ Doctors rely on drug companies to provide them with truthful information about the risks and benefits of their products, and they are influenced by their patients’ requests for particular drugs.

127. The Manufacturer Defendants spent millions of dollars to market their drugs to prescribers and patients and meticulously tracked their return on that investment. In one recent survey published by the AMA, even though nine in ten general practitioners reported prescription drug abuse to be a moderate to large problem in their communities, 88% of the respondents said they were confident in their prescribing skills, and nearly half were comfortable using opioids for chronic non-cancer pain.⁴⁶

128. These results are directly due to the Manufacturer Defendants’ fraudulent marketing campaign, which included:

- misrepresenting the truth about how opioids lead to addiction;
- misrepresenting that opioids improve function;
- misrepresenting that addiction risk can be managed;

⁴⁵ See, e.g., Manchanda, P. & Chintagunta, P.K. Marketing Letters (2004) 15: 129; Larken, Ian et al., “Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children,” *Health Affairs* 33, no.6 (2014):1014-1023 (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in on-label use of promoted drugs). See also Van Zee, Art, “The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy.” *American Journal of Public Health* 99.2 (2009): 221–227. PMC (noting an increase of OxyContin prescriptions from 670,000 annually in 1997 to about 6.2 million in 2002 and an approximate doubling of Purdue’s internal sales force from 1996 to 2000).

⁴⁶ Hwang, Catherine S. et al., “Prescription Drug Abuse A National Survey of Primary Care Physicians,” *JAMA Intern Med.* 2015;175(2):302–304.

- deceiving doctors, patients, and payors through misleading terms like “pseudoaddiction”;
- falsely claiming that opioid withdrawal and dependency are simply managed;
- misrepresenting that increased doses pose no significant additional risks; and
- falsely omitting or minimizing the adverse effects of opioids and overstating the risks of alternative forms of pain treatment.

129. Underlying each of the Manufacturer Defendants’ misrepresentations and deceptions in promoting the long-term continuous use of opioids to treat chronic pain was Manufacturer Defendants’ collective effort to hide from the medical community the fact that no adequate and well-controlled studies of long-term opioid use exist.⁴⁷

A. Purdue

i. Purdue set out to end medical providers’ long-standing fear of prescribing opioids

130. Up until the mid-1990s, physicians prescribed opioids primarily to cancer patients and persons recovering from surgery. Fearful of the addictive qualities of opioids, physicians would not generally prescribe them for long term chronic pain. As detailed in a review of the development of the opioid crisis published in the 2015 Annual Review of Public Health, “[p]rior to the introduction of OxyContin [by Purdue in 1995], many physicians were reluctant to prescribe OPRs [opioid pain relievers] on a long-term basis for common chronic conditions

⁴⁷ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing*, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

because of their concerns about addiction, tolerance, and physiological dependence.”⁴⁸

131. Purdue’s own research confirmed the mid-1990s consensus of medical providers regarding the dangers of opioids. According to the Agreed Statement of Facts signed by Purdue in connection with its 2007 guilty plea to federal criminal charges for misbranding OxyContin: “During the period February through March 1995, PURDUE supervisors and employees obtained market research that included focus groups of forty primary care physicians, rheumatologists, and surgeons to determine their receptivity to using OxyContin for non-cancer pain... **‘[t]he biggest negative of [OxyContin] was the abuse potential.’**”⁴⁹

132. As Purdue prepared to introduce OxyContin to the U.S. market, including New York, it carefully evaluated physicians’ concerns about the risks of addiction associated with opioids and embarked on a highly successful, fraudulent campaign to convince physicians that OxyContin created minimal risk of addiction. As Purdue’s efforts demonstrated success in the form of rapid increases in opioid prescribing, Mallinckrodt, and other opioid manufacturers joined Purdue in its fraudulent scheme.

ii. Purdue’s aggressive marketing of OxyContin fueled ever-increasing, and excessive, demand for the drug

133. From the outset of its nationwide OxyContin marketing campaign, Purdue “aggressively” promoted the drug to physicians both inside and outside of New York for non-cancer pain conditions that can be caused by arthritis, injuries, and chronic diseases.⁵⁰ Essential

⁴⁸ Andrew Kolodny, et al., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 36 Ann. Rev. Pub. Health 559, 562. (2015).

⁴⁹ Information as to *Purdue Frederick Co., Inc., U.S.A v. Purdue Frederick Co., Inc.*, No. 1:07-cr-00029, W.D. Va. May 10, 2007, ECF No. 5-2 at ¶19 (alteration in original).

⁵⁰ Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 Am. J. Pub. Health 221, 222 (2009) [hereinafter *Van Zee*] (quoting Purdue’s 1999 OxyContin Marketing Plan); see also U.S. Gov’t Accounting Office, Report to Cong. Requesters,

to this marketing strategy was Purdue's claim, which it later conceded to be fraudulent, that OxyContin rarely gave rise to addiction, a risk Purdue downplayed as likely in "less than one percent of patients."⁵¹

134. Purdue's promotion of OxyContin for the treatment of non-cancer-related pain contributed to a "nearly tenfold" increase in OxyContin prescriptions for non-cancer-related pain, from about 670,000 prescriptions in 1997 to about 6.2 million prescriptions in 2002.⁵²

135. Purdue's marketing for OxyContin was bolstered by the bold claim that the drug was "the first and only 12-hour OxyContin pain medicine."⁵³ In a 1996 press release, Purdue touted: "Unlike short-acting pain medications, which must be taken every 3 to 6 hours – often on an 'as needed' basis – OxyContin Tablets are taken every 12 hours, providing smooth and sustained pain control all day and all night."⁵⁴ That same press release included a "Background" section, which proclaimed that the "fear of addiction" to opioids was "exaggerated" and "largely unfounded."⁵⁵

136. When it introduced OxyContin, Purdue had no meaningful evidence that supported its core claim that the drug's addiction risk was minimal. It later admitted that this claim was

Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem 17 (2003) [hereinafter OxyContin Abuse and Diversion].

⁵¹ OxyContin Abuse and Diversion, at 28.

⁵² *Id.* at 18.

⁵³ Press Release, Purdue Pharma L.P., New Hope for Millions of Americans Suffering from Persistent Pain (May 31, 1996), *available at* <https://assets.documentcloud.org/documents/2815975/Pressreleaseversionone.pdf>; *see also* Minutes from the OxyContin Launch Team Meeting (Mar. 31, 1995), *available at* <http://documents.latimes.com/oxycontin-launch-1995/>.

⁵⁴ *Id.*

⁵⁵ *Id.*

fraudulent.⁵⁶

137. Purdue also had extensive evidence that its “12-hour relief” claims were false. This was critical because patients who could not get 12-hour relief would supplement their dosage, thereby increasing their risk of addiction.⁵⁷

138. Even before OxyContin went on the market, Purdue’s clinical trials showed many patients were not getting 12 hours of relief from a single dose. The first clinical study of OxyContin – which was designed and paid for by Purdue, and overseen by Purdue scientists – occurred in 1989 and involved women recuperating from abdominal and gynecological surgery at two hospitals in Puerto Rico. In that study, 90 women were given a single dose of OxyContin while other patients were given short-acting painkillers or placebos. More than a third of women given OxyContin started complaining of pain after just eight hours, and about half required more medication before the 12-hour mark.⁵⁸

139. The results of the 1989 study were not unique. Dr. Daniel Brookoff, a New York pain specialist whom Purdue selected to field-test OxyContin, ran into similar issues. In a 1995 clinical study completed as part of the Food and Drug Administration (“FDA”) approval process, Dr. Brookoff eventually moved 8 of 15 chronic pain patients to 8-hour dosing because they were not getting adequate relief taking the drug twice a day.⁵⁹

140. Purdue nevertheless launched an extensive campaign to market and promote the drug using an expanded sales force and multiple promotional approaches to encourage physicians,

⁵⁶ Clay Duda, *On the Front Lines of Knoxville’s Battle Against Opiate Addiction*, knoxvillemercury.com, June 1, 2016, <http://www.knoxmercury.com/2016/06/01/front-lines-knoxvilles-battle-opiate-addiction/>.

⁵⁷ Harriet Ryan et al., *‘You Want a Description of Hell?’ OxyContin’s 12-Hour Problem*, latimes.com, May 5, 2016, <http://www.latimes.com/projects/oxycontin-part1/>.

⁵⁸ *Id.* (citing original documents from the study).

⁵⁹ *Id.*

including primary care specialists, to prescribe OxyContin as an initial opioid treatment for non-cancer pain.⁶⁰ This campaign was nationwide and directed at medical providers and potential consumers in New York, among other states.

141. Utilizing marketing data, Purdue and its sales representatives pushed the false narrative that OxyContin, because of its time-release formulation, posed a lower threat of abuse and addiction to patients than traditional, shorter-acting painkillers like Percocet or Vicodin.⁶¹

142. To this end, Purdue used a series of deceptive videos and journal advertisements. For example, in 1998, Purdue distributed 15,000 copies of an OxyContin marketing video to physicians without submitting it to the FDA for review, as required under the Federal Food Drug and Cosmetic Act (“FD&C Act”).⁶² In the Purdue video, entitled *I Got My Life Back: Patients in Pain Tell Their Story*, a physician **“stated that opioid analgesics have been shown to cause addiction in less than 1 percent of patients.”**⁶³ That statement, according to the FDA, **“has not been substantiated.”**⁶⁴

143. In 2000, Purdue submitted a different promotional video to the FDA, this one entitled *I Got My Life Back: A Two Year Follow up of Patients in Pain*.⁶⁵ **The FDA found that Purdue’s video “appeared to make unsubstantiated claims regarding OxyContin’s effects on patients’ quality of life and ability to perform daily activities and minimized the risks**

⁶⁰ OxyContin Abuse and Diversion at 16-24.

⁶¹ Press Release, U.S. Attorney’s Office W.D. Va., *The Purdue Frederick Company, Inc. and Top Executives Plead Guilty to Misbranding OxyContin: Will Pay Over \$600 Million* (May 10, 2007), available at <https://health.mil/Reference-Center/Publications/2007/05/10/The-Purdue-Frederick-Company-Inc-and-Top-Executives-Plead-Guilty>. [hereinafter WV Press Release].

⁶² OxyContin Abuse and Diversion at 27.

⁶³ *Id.* at 28.

⁶⁴ *Id.*

⁶⁵ *Id.*

associated with the drug.”⁶⁶ Ignoring the FDA’s concerns, Purdue distributed 12,000 copies of the videos to physicians.⁶⁷

144. Purdue also employed false or misleading medical journal advertisements that, as determined by the FDA, violated the FD&C Act. Notably, in January 2003, the FDA issued a stern warning letter to Purdue in response to two ads the company ran in the *Journal of the American Medical Association*, a prestigious publication distributed to physicians in New York and throughout the United States:

Your journal advertisements omit and minimize the serious safety risks associated with OxyContin and promote it for uses beyond which have been proven safe and effective. Specifically, your journal advertisements fail to present in the body of the advertisements any information from the boxed warning in the approved product labeling (PI) for OxyContin regarding the potentially fatal risks associated with the use of OxyContin and the abuse liability of OxyContin, which is a Schedule II controlled substance, and make unsubstantiated efficacy claims promoting the use of OxyContin for pain relief. Your journal advertisements also understate the minimal safety information that is presented. **Your advertisements thus grossly overstate the safety profile of OxyContin by not referring in the body of the advertisements to serious, potentially fatal risks associated with OxyContin, thereby potentially leading to prescribing of the product based on inadequate consideration of risk.** In addition, your journal advertisements fail to present in the body of the advertisements critical information regarding limitations on the indicated use of OxyContin, thereby promoting OxyContin for a much broader range of patients with pain than are appropriate for the drug. **The combination in these advertisements of suggesting such a broad use of this drug to treat pain without disclosing the potential for abuse with the drug and the serious, potentially fatal risks associated with its use, is especially egregious and alarming in**

⁶⁶ *Id.*

⁶⁷ *Id.*

its potential impact on the public health.⁶⁸

145. The message that the FDA deemed “egregious and alarming” – that OxyContin posed little risk of addiction and was thus appropriate for chronic non-cancer pain – was critical to Purdue’s sales and central to Purdue’s marketing efforts directed at prescribing physicians in New York and throughout the United States. Purdue aggressively sought to influence physicians’ prescribing habits by inviting them to all-expenses-paid conferences. From 1996 to 2000, Purdue conducted more than 40 national pain management and speaker training conferences at resorts in Florida and Arizona.⁶⁹ Before that practice was discontinued, more than 5,000 physicians, pharmacists, and nurse practitioners from New York and elsewhere attended Purdue’s conferences, where they were recruited and trained for Purdue’s national speaker bureau.⁷⁰

146. Beginning in 1996, Purdue hired 318 sales representatives to implement its OxyContin marketing campaign.⁷¹ By 2000, the number of sales representatives directly employed by Purdue had risen to 562, and Purdue added a Hospital Specialty Division which employed another 109 sales representatives.⁷² At that time, the 671 Purdue sales representatives had a total physician call list of approximately 33,400 to 44,500 physicians.⁷³

147. Purdue had a lucrative bonus system which incentivized its sales representatives to increase sales of OxyContin in their respective territories. In 2001, in addition to the average sales

⁶⁸ Letter from Thomas W. Abrams, FDA, Dir. of Drug Mktg. Adver. and Comm’n, to Michael Friedman, Exec. Dir. Purdue Pharma, L.P. (Jan. 17, 2003), *available at* <http://wayback.archive-it.org/7993/20170112065652/http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM168946.pdf>.

⁶⁹ OxyContin Abuse and Diversion at 22.

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² *Id.* at 19-20.

⁷³ *Id.* at 20.

representative's annual salary of \$55,000, annual bonuses averaged \$71,500, with a range of \$15,000 to nearly \$240,000.⁷⁴ Purdue paid approximately \$40 million in bonuses tied to OxyContin sales in 2001.⁷⁵

148. Purdue also entered into a co-promotion agreement with Abbott Laboratories ("Abbott"), through which Abbott provided an additional 300 sales representatives per year from 1996 through 2002.⁷⁶ The sales representatives from the two companies closely coordinated their efforts, met regularly to strategize, and shared marketing materials.⁷⁷ Internal Abbott and Purdue memos, as well as sales documents and marketing materials, show that Abbott sales representatives were instructed to downplay the threat of addiction with OxyContin and make other claims to doctors that had no scientific basis.⁷⁸ For example, in one internal Abbott memo, which listed ideas to help sales personnel increase OxyContin's share of pain-pill prescriptions written by orthopedic surgeons, Abbott told its sales representatives to highlight the "less abuse/addiction potential" of the drug, which could be taken just twice a day because of its time-release formulation.⁷⁹

149. The more Abbott generated in OxyContin sales, the higher the reward for the company. Under the agreement with Purdue, Abbott received 25 percent of all net sales, up to \$10 million, for prescriptions written by doctors its sales reps called on, and 30 percent of sales above

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ *Id.* at 19-20.

⁷⁷ David Armstrong, *Secret trove reveals bold 'crusade' to make OxyContin a blockbuster*, STAT News, September 22, 2016.

⁷⁸ *Id.*

⁷⁹ *Id.*

\$10 million.⁸⁰ Accordingly, similar to Purdue, Abbott heavily incentivized its sales staff to push OxyContin, offering \$20,000 cash prizes and luxury vacations to top performers.⁸¹

150. One of the “critical foundations” of Purdue and Abbott’s marketing for OxyContin was the use of sophisticated marketing data to influence physicians’ prescribing habits.⁸² By compiling prescriber profiles on individual physicians, the co-promoters were able to identify the highest and lowest prescribers of particular drugs in a single zip code, county, state, or the entire country.⁸³ Purdue and Abbott then targeted the highest, and in some cases the least discriminate, prescribers of opioids across the country.⁸⁴

151. Purdue and Abbott spent hundreds of millions of dollars promoting OxyContin through their respective sales forces because they understand that their representatives’ sales pitches are effective. Numerous studies indicate that marketing can and does impact doctors’ prescribing habits, and face-to-face detailing has the highest influence on intent to prescribe.⁸⁵ Purdue and Abbott could see this phenomenon at work not only in the aggregate, as their sales climbed with their promotional spending, but also at the level of individual prescribers, whom they targeted for detailing and who responded by prescribing more OxyContin. With Abbott’s help,

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 Am. J. Pub. Health 221, 222 (2009) [hereinafter *Van Zee*].

⁸³ *Id.*

⁸⁴ *Id.*

⁸⁵ Puneet Manchanda & Pradeep K. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 (2-3) Mktg. Letters 129 (2004) (detailing has a positive impact on prescriptions written); Ian Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33(6) Health Affairs 1014 (2014) (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in 34% decline in on-label use of promoted drugs); *see also* Van Zee at 222 (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997 to 6.2 million in 2002 to a doubling of Purdue’s sales force and trebling of annual sales calls).

sales of OxyContin went from a mere \$49 million in its first full year on the market to \$1.6 billion in 2002.⁸⁶ Over the life of the co-promotional agreement, Purdue paid Abbott nearly half a billion dollars.⁸⁷

152. As part of its direct marketing campaign, Purdue distributed several types of branded promotional items to health care professionals.⁸⁸ Among the items were OxyContin fishing hats, stuffed plush toys, music compact discs (entitled “Get in the Swing With OxyContin”), and pens containing a pullout conversion chart showing physicians how to calculate the dosage to convert a patient to OxyContin from other opioid pain relievers.⁸⁹ **According to the U.S. Drug Enforcement Agency (“DEA”), the “use of such branded promotional items for a Schedule II opioid [was] unprecedented... and indicates Purdue’s aggressive, excessive, and inappropriate marketing of their product, OxyContin.”**⁹⁰

153. Akin to practices employed by street drug dealers, Purdue also gave away its addictive product to first-time users. “For the first time in marketing any of its products, Purdue used a patient starter coupon program for OxyContin to provide patients with a free limited-time prescription.”⁹¹ Under this program, Purdue’s sales representatives distributed coupons to physicians who, in turn, decided whether to offer one to a patient, and then the patient could redeem a free prescription through a participating pharmacy. Approximately 34,000 coupons had been redeemed nationally when the program was terminated following the July 2001 OxyContin label change.

⁸⁶ David Armstrong, *Secret trove reveals bold ‘crusade’ to make OxyContin a blockbuster*, STAT News, September 22, 2106.

⁸⁷ *Id.*

⁸⁸ OxyContin Abuse and Diversion at 25.

⁸⁹ *Id.*

⁹⁰ *Id.* at 56.

⁹¹ *Id.* at 23.

154. In conjunction with its direct marketing efforts, Purdue began an innovative indirect-marketing campaign for OxyContin. Because FDA regulations prohibit direct-to-consumer advertising of narcotics, Purdue decided to concentrate on “nonbranded education,” which would market the concept of pain relief to consumers. To this end, in 1997, the company launched the “Partners Against Pain” website available to consumers in New York and throughout the United States.⁹² Through a variety of articles, studies, and polls, the “Partners Against Pain” website “promoted three ideas to doctors and patients: that pain was much more widespread than had previously been thought; that it was treatable; and that in many cases it could, and should, be treated with opioids.”⁹³

155. Purdue also used paid third parties to give its marketing claims a perception of scientific legitimacy. To this end, as explained in a recently published history of the opioid crisis, “Purdue provided financial support to the [APS], the [AAPM], the [FSMB], pain patient groups, and other organizations. In turn, these groups all advocated for more aggressive identification and treatment of pain, especially use of OPRs [opioids].”⁹⁴

156. “To overcome what they claimed to be ‘opiophobia,’ physician-spokespersons for opioid manufacturers published papers and gave lectures in which they claimed that the medical community had been confusing addiction with ‘physical dependence.’ They described addiction as rare and completely distinct from so called ‘physical dependence,’ which was said to be clinically unimportant. They cited studies with serious methodological flaws to highlight the

⁹² *Id.* at 23-24.

⁹³ Paul Tough, *The Alchemy of OxyContin*, nytimes.com, July 29, 2001, <http://www.nytimes.com/2001/07/29/magazine/the-alchemy-of-oxycontin.html>.

⁹⁴ Andrew Kolodny, et al., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 36 Ann. Rev. Pub. Health 559, 562. (2015).

entirely false claim that the risk of addiction was less than 1%.”⁹⁵

157. For example, in 1996, the APS and the AAPM – who were funded in part by the Manufacturer Defendants – issued a “consensus statement” that “suggested that opioids were safe and effective for chronic, noncancer pain and that the risk of addiction was low.”⁹⁶

158. The co-authors of the Consensus Statement were David Joranson, MSSW, then founder and distinguished scientist of the Pain and Policy Studies Group at the University of Wisconsin School of Medicine and Public Health, and Haddox. Between 2000 and 2010, Joranson’s Pain and Policy Studies Group received approximately \$1.6 million in grants from Purdue.⁹⁷ As detailed in an investigative series in the Milwaukee Journal Sentinel, the group became a consistent cheerleader for the widespread prescriptions of opioids. When he co-authored the Consensus Statement, Haddox was a paid speaker for Purdue. He was hired by Purdue in 1999 and has continued to be a Purdue executive ever since.⁹⁸

iii. Purdue’s 2007 guilty plea for lying about OxyContin, and its continued marketing of the drug

159. **In 2007, Purdue and its three top executives were indicted and forced to plead guilty to wide ranging fraud in falsely promoting OxyContin as non-addictive and appropriate for chronic pain.** Purdue’s extensive fraud during the first two decades of its OxyContin campaign are thus an uncontroversial matter of public record admitted by the company.

160. As United States Attorney John L. Brownlee explained in a 2007 news release:

⁹⁵ *Id.*

⁹⁶ John Fauber, *Academics Profit by Making the Case for Opioid Painkillers*, abcnews.go.com, Apr. 4, 2011, abcnews.go.com/Health/academics-profit-making-case-opioid-painkillers/story?id=13284493.

⁹⁷ *Id.*

⁹⁸ *Id.*

“Even in the face of warnings from health care professionals, the media, and members of its own sales force that OxyContin was being widely abused and causing harm to our citizens, Purdue, under the leadership of its top executives, continued to push a fraudulent marketing campaign that promoted OxyContin as less addictive, less subject to abuse, and less likely to cause withdrawal.”⁹⁹

161. As part of its 2007 felony guilty plea for misbranding OxyContin as less addictive and appropriate for chronic pain, Purdue admitted that:

Purdue supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications, as follows:

[t]rained Purdue sales representatives and told some health care providers that it was more difficult to extract the OxyContin from an oxycodone tablet for the purpose of intravenous abuse, although Purdue’s own study showed that a drug abuser could extract approximately 68% of the oxycodone from a single 10mg OxyContin tablet by crushing the tablet, stirring it in water, and drawing the solution through cotton onto a syringe;

[t]old Purdue sales representatives they could tell health care providers that OxyContin potentially creates less chance for addiction than immediate-release opioids,[which the company knew was not true]; ...

[s]ponsored training that taught Purdue sales supervisors that OxyContin had fewer ‘peak and trough’ blood level effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids, [which the company knew was not true];

[falsely] [t]old certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug; and

[falsely] [t]old certain health care providers that OxyContin did not cause a ‘buzz’ or euphoria, caused less euphoria, had less addiction

⁹⁹ WV Press Release, *supra* note 48 (quoting U.S. Attorney John Brownlee).

potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to ‘weed out’ addicts and drug seekers.¹⁰⁰

162. As Purdue admitted in its 2007 guilty plea, these claims about OxyContin were entirely fraudulent. Nevertheless, for over 20 years they had been at the center of an unprecedented multi-million-dollar marketing campaign designed to convince physicians to disregard their longstanding unwillingness to prescribe opioids for any medical conditions other than late stage cancer and other acute, or short-term, conditions.

163. Under the plea agreement, Purdue also agreed to pay \$600 million in criminal and civil penalties – one of the largest settlements in history for a drug company’s marketing misconduct.¹⁰¹

164. At the same time Purdue’s president, top lawyer, and medical director pled guilty as individuals to criminal misbranding¹⁰² and agreed to pay a total of \$34.5 million in fines.¹⁰³

165. Under the plea agreement, Purdue also entered into a Corporate Integrity Agreement (“CIA”) with the United States Department of Health and Human Services – Office of Inspector General (“HHS-OIG”).¹⁰⁴ As part of the CIA, Purdue agreed to refrain from deceptively marketing OxyContin, to train its employees regarding compliance with the CIA, and to report its compliance (both independently and through an independent review organization) to the HHS-

¹⁰⁰ *U.S. v. The Purdue Frederick Company, Inc.*, Case No. 1:07-cr-00029, Dkt. 5-2 (Agreed Statement of Facts) at ¶ 20 (W.D. Va. May 10, 2017).

¹⁰¹ *U.S. v. Purdue Frederick Co., Inc.*, 495 F. Supp. 2d 569, 571-72 (W.D. Va. 2007).

¹⁰² “Misbranding” is a broad statute that makes it a crime to mislabel a drug, fraudulently promote it or market it for an unapproved use.

¹⁰³ Barry Meier, *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, nytimes.com, May 10, 2007, <http://www.nytimes.com/2007/05/10/business/11drug-web.html>.

¹⁰⁴ Information as to Purdue Frederick Co., Inc., *U.S.A v. Purdue Frederick Co., Inc.*, No. 1:07-cr-00029, W.D. Va. May 10, 2007, ECF No. 5-5.

OIG.¹⁰⁵

iv. Even after its guilty plea, Purdue continued its false and misleading marketing practices aided by the other Manufacturer Defendants

166. Despite its guilty plea, Purdue has continued to deceptively market opioids, feeding the opioid addiction crisis set in motion by its fraudulent advertising. As a result, sales of OxyContin were not only unhindered by the guilty plea – they continued to grow. OxyContin yielded \$3.1 billion in revenue for Purdue in 2010, which was nearly four times its 2006 sales of \$800 million.¹⁰⁶ The Manufacturer Defendants joined in this effort.

167. Purdue continued to aggressively push the same false narrative for which it had been criminally prosecuted – that, to quote its statement of facts accompanying its guilty plea, “OxyContin was less addictive, less subject to abuse” than traditional opioids, and therefore appropriate for treatment of long-term chronic pain.

168. To evade scrutiny, Purdue continued to use third parties – with which it was closely tied financially – to convey its pro-OxyContin message.

169. In addition to using front groups, Purdue masked its effort to continue the promotion of widespread opioid prescribing by presenting the decision to use opioids for chronic pain not as a highly risky practice with no scientific support – the truth – but rather as a complex determination that required extensive analysis of each individual patient. There was no scientific basis for this position, which effectively justified continued widespread opioid prescribing for virtually any patient, thereby allowing Purdue’s fraudulent marketing campaign to continue after 2007, as if the guilty plea had not occurred.

¹⁰⁵ *Id.*

¹⁰⁶ Katherin Eban, *OxyContin: Purdue Pharma’s Painful Medicine*, Fortune.com, Nov. 9, 2011, <http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/>.

170. For example, in December 2009, medical education materials paid for by opioid manufacturers, including Purdue (1) reiterated Purdue’s core fraudulent claim that “addiction is rare in patients who become psychologically dependent on opioids while using them for pain control,” (2) emphasized the need to individually evaluate each patient “as clinical trials [rejecting opioid treatment]are not designed to identify the best treatment regimen in a given situation to manage chronic pain,” and (3) urged use of opioids even for patients engaging in “aberrant behaviors” while setting the following extreme standard to be used to identify individual patients with addiction problems: “a patient exhibiting egregious behaviors that persist, despite repeated warnings and that require significant time and resources to manage, is likely to have a problem with abuse and possibly addiction.” The materials further stated that “[a]n opioid trial is the only way a clinician can determine the efficacy and tolerability of a particular agent in a particular person” – in other words, the only way to rule out opioids for any given chronic pain patient was to give opioids a try. Not one of these assertions has ever been supported by science. Though “expired,” the materials are still available on the Internet today.¹⁰⁷

171. In the same vein, Purdue-funded key opinion leader Dr. Russell Portenoy, speaking on Good Morning America in 2010, stated categorically that “[a]ddiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted.” As detailed in the scientific background section of this complaint, Dr. Portenoy’s bold assertion was directly contrary to the scientific evidence. Dr. Portenoy, who himself is facing

¹⁰⁷ Anderson *et al*, “Opioid Prescribing: Clinical Tools and Risk Management Strategies, available at https://mn.gov/boards/assets/Opioid_Prsecibing_Clinical_Tools_and_Risk_Management_Strategies.pdf_tcm21-366993.pdf.

lawsuits for his work as a Purdue-paid opioid pitchman, has now conceded that this promotion of opioids for chronic pain was “clearly the wrong thing to do.” He is on record stating: “I gave innumerable lectures in the late 1980s and 90’s about addiction that weren’t true.”¹⁰⁸ But the damage has long since been done.

172. Another opioid pitchman, Dr. Lynn Webster, in 2010 disclosed serving on Purdue’s Medical Advisory Board. During the period of 2013 through 2015, Dr. Lynn Webster was the principle researcher on over \$9 million in contracts with pharmaceutical companies, including Mallinckrodt. Dr. Lynn Webster created a webinar out of a presentation he gave in Las Vegas, Nevada on September 22, 2011. In the Webinar, which remained available on the Internet on June 12, 2017, Webster promoted “Single-entity opioids (oxycodone, fentanyl)” for treatment of chronic pain.¹⁰⁹ The seminar was, according to Dr. Webster, funded by a “generous education grant” from Purdue.

173. In 2016 and 2017, Webster also produced and distributed a 57-minute documentary, “The Painful Truth,” which continues to promote the use of opioids to treat chronic non-cancer pain. “The Painful Truth” tries to excuse Dr. Webster’s role in unleashing America’s opioid addiction crises by featuring chronic pain patients expressing their fears about losing access to opioids.¹¹⁰

174. The 2010 annual report of the Manufacturer Defendants-funded APF, which has been described by the President of Physicians Responsible Opioid Prescribing as “a front for

¹⁰⁸ Thomas Catan & Evan Perez, *A Pain Champion has Second Thoughts*, wsj.com, Dec. 17, 2012, <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>.

¹⁰⁹ See generally Emerging Solutions, <http://emergingsolutionsinpain.com/> (last visited June 12, 2017).

¹¹⁰ David Armstrong, *TV Documentary on Pain Treatment Funded by Doctor with Industry Ties*, statnews.com, Mar. 24, 2017, <https://www.statnews.com/2017/03/24/pain-documentary-public-television/>.

opioid manufacturers,”¹¹¹ carefully documents the scope of the Manufacturer Defendants’ fraudulent enterprise. This 2010 report details thousands of pro-opioid advertisements, public statements, letters, Facebook Posts, and similar communications. For example, the report states: “Through online, print, radio, and television outlets, APF’s local and national media outreach efforts secured 1,600 media stories on pain in 2010 – an increase of 1,255% from 2009. Reaching more than 600 million people with important pain-related messages, APF spokespeople and advocates provided education, information and assistance to people with pain and combated the negative stereotypes and stigmas associated with pain.”¹¹²

175. To this day, Purdue publishes an OxyContin website for physicians promoting OxyContin for patients with chronic pain – even those with a history of substance abuse. The site provides an example of a person suffering “sciatic nerve pain” with a history of substance abuse and states: “Risks are increased in patients with personal or family history of substance abuse ... [t]he potential for these risks should not, however, prevent the proper management of pain in any given patient. Patients at increased risk may be prescribed opioids such as OxyContin.”¹¹³

176. These are not isolated statements, but just a select few representative examples of fraudulent pro-opioid communications that formed part of a vast, multi-year fraud designed to fuel the improper marketing of opioids following Purdue’s guilty plea by misrepresenting addiction risks and fraudulently promoting the entirely unscientific practice of using opioids for non-acute

¹¹¹ Charles Ornstein and Tracy Weber, *Patient Advocacy Group Funded by Success of Painkiller Drugs, Probe Finds*, washingtonpost.com, Dec. 23, 2011. Available at: https://www.washingtonpost.com/national/health-science-/patient-advocacy-group-funded-by-success-of-painkiller-drugs-probe-finds/2011/12/20/gIQAgvczDP_story.html.

¹¹² American Pain Fund 2010 Annual Report. Available at: https://archive.org/stream/277604-apf-2010-annual-report/277604-apf-2010-annual-report_djvu.txt.

¹¹³ About OxyContin. Available at: <http://www.purduepharma.com/healthcare-professionals/products/oxycontin/> (last visited June 12, 2017).

long-term chronic pain.

177. The net effect of the Manufacturer Defendants' pro-opioid communications effort has been to continue the broad dissemination of the very lies for which Purdue pled guilty in 2007 up through this very day, thereby ensuring that the continuous flow of opioids to New York and communities throughout Rockland County without interruption.

178. Speaking before the House Opioid Task Force in 2017, Dr. Michael Baron of the New York Board of Medical Examiners summed up the cumulative effect of the opioid manufacturers' multi-year fraud:

We came out with what I call 'Generation O.' A whole generation of physicians that were taught it's ok to prescribe opiates, that they're safe, and that it's what the patient wants. But we bypassed evidence-based medicine. The whole medical system was hijacked by industry and really greed.

The triggers of the opioid epidemic were really the pharmaceutical industry and pain experts that were on the payroll of the pharmaceutical industry. And they preached that opioids are safe and effective for chronic, non-cancer pain, the risk of addiction is rare, and opioid therapy can be easily discontinued, all of which is nonsense.¹¹⁴

v. Purdue profited from the abuse and diversion of OxyContin

179. The high availability of OxyContin correlated with increased addiction, abuse, and diversion (a term used to describe the redistribution of prescription drugs for illegal uses), and by 2004 OxyContin had become a leading drug of abuse in the United States.¹¹⁵

¹¹⁴ House Opioid Task Force, February 23, 2017.

¹¹⁵ Van Zee at 221.

180. The increasing rates of addiction and abuse sustained OxyContin’s remarkable commercial success.¹¹⁶ As the DEA has explained, OxyContin abusers learned how to simply crush the controlled-release tablet and swallow, inhale, or inject the high-potency opioid for an intense morphine-like high.¹¹⁷ Purdue was well aware of this risk of diversion and abuse in this manner as early as 1995, because the company’s own testing demonstrated that 68% of the oxycodone could be extracted from an OxyContin tablet when crushed.¹¹⁸

181. In a November 2003 letter to the General Accounting Office (“GAO”), the DEA provided the following explanation of the causes and factors relating to the diversion of OxyContin:

The DEA has previously stated that the company’s [i.e. Purdue’s] aggressive methods, calculated fueling of demand and the grasp for major market share very much exacerbated OxyContin’s widespread abuse and diversion. While Purdue highlights its funding of pain-related educational programs and websites and its partnership with various organizations, the fact remains that Purdue’s efforts – which may be viewed as self-serving public relations damage control – would not have been necessary had Purdue not initially marketed its product aggressively and excessively. Contributing to the abuse and diversion problem (and the product’s excessive availability) is the fact that in promoting this drug to practitioners, Purdue deliberately minimized the abuse risk associated with OxyContin The claim in Purdue’s “educational” video for physicians that opioid analgesics cause addiction in less than one percent of patients is not only unsubstantiated but also dangerous because it misleads

¹¹⁶ *Id.* at 223.

¹¹⁷ Drug Enforcement Administration, Office of Diversion Control, Action Plan to Prevent the Diversion and Abuse of OxyContin, https://web.archive.org/web/20080512200957/https://www.deadiversion.usdoj.gov/drugs_concern/OxyContin/abuse_oxy.htm (accessed May 4, 2017) [hereinafter *DEA OxyContin Action Plan*].

¹¹⁸ Information as to *Purdue Frederick Co., Inc., U.S.A v. Purdue Frederick Co., Inc.*, No. 1:07-cr-00029, W.D. Va. May 10, 2007, ECF No. 5-5; *see also* Van Zee at 223.

prescribers.¹¹⁹

182. More recently, a 2013 article in the L.A. Times revealed that, since at least 2002, Purdue has maintained a database of 1,800 doctors suspected of recklessly prescribing the company's pills to addicts and drug dealers.¹²⁰ Purdue refers to the confidential list as "Region Zero" in internal documents.¹²¹ In all but a few cases, Purdue did not alert law enforcement or medical authorities to the doctors on its list, many of whom were prolific prescribers of OxyContin.¹²²

183. The example of Dr. Elanor Santiago, one of the physicians on Purdue's "Region Zero" list, provides a stunning display of the causal relationship between the prescription market and diverted market for OxyContin, as well as Purdue's willful and knowing decision to profit from the diversion problem.

184. Beginning in the summer of 2008, Dr. Santiago, an elderly physician, ran the Lake Medical "clinic" (set up by an ex-con and his business partner) out of office space on a seedy block near MacArthur Park in Los Angeles.¹²³ Dr. Santiago immediately began prescribing OxyContin in extraordinary quantities. In a single week in September 2008, she issued orders for 1,500 pills, more than entire pharmacies sold in a month. In October, it was 11,000 pills. By December, she had prescribed more than 73,000, with a street value of nearly \$6 million. Purdue tracked the surge in prescriptions, and eventually sent Michele Ringler, the district sales manager for Los Angeles,

¹¹⁹ *Id.* at 56.

¹²⁰ Scott Glover & Lisa Girion, *OxyContin Maker Closely Guards Its List of Suspect Doctors*, latimes.com, Aug. 11, 2013, <http://articles.latimes.com/2013/aug/11/local/la-me-rx-purdue-20130811>.

¹²¹ *Id.*

¹²² *Id.* (noting that Purdue purportedly alerted law enforcement or medical regulators to 154 of the suspected prescribers – about 8% of those in its database).

¹²³ Harriet Ryan et al., *More than 1 million OxyContin Pills Ended up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, latimes.com, July 10, 2016, <http://www.latimes.com/projects/la-me-oxycontin-part2/>.

to check out the clinic as part of the company's investigation. When Ringler and one of her sales reps arrived, they found a building that looked abandoned, according to company emails recounting the visit. Inside, the hallways were strewn with trash and lined with a crowd of men who looked like they "just got out of L.A. County jail." Feeling uncomfortable, Ringler and the rep left without speaking to Dr. Santiago. When a Purdue security committee met in Stamford in December 2008, less than five months after Lake Medical opened, Dr. Santiago was under review, according to internal records and interviews. The panel, comprised of three company lawyers, could have reported Dr. Santiago to the DEA. Instead it opted to add her name to the "Region Zero" list of physicians suspected of recklessly prescribing OxyContin to addicts or dealers. As Purdue's investigation of the clinic continued, the company eventually concluded that Lake Medical was working with a corrupt pharmacy in Huntington Park to obtain large quantities of OxyContin. In a September 1, 2009 email Purdue district sales manager Ringler sent to company officials, she referred to the Lake Medical clinic and corrupt pharmacy as "an organized drug ring," and suggested that Purdue contact the DEA. Nevertheless, Purdue did not shut off the supply of highly addictive OxyContin and did not tell authorities what it knew about Lake Medical until several years later when the clinic was out of business and its leaders indicted. By that time, 1.1 million pills had spilled into the hands of Armenian mobsters, the Crips gang, and other criminals.¹²⁴

185. Dr. Santiago's case is just one of many that demonstrate that Purdue did not use its database of suspected physicians to reduce OxyContin abuse, to rein in dangerous physicians, or to stop the unlawful distribution of opioids. Instead, Purdue knowingly aided criminal activity in order to maximize its own profits.

¹²⁴ *Id.*

vi. Purdue failed to prevent diversion and to monitor, report, and stop suspicious orders of OxyContin as required

186. Purdue, as with all the Manufacturer Defendants, is under the same federal law duties as the Distributor Defendants to prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids.

187. Like the Distributor Defendants, Purdue was required to register with the DEA to manufacture schedule II controlled substances, like prescription opioids.¹²⁵ A requirement of such registration is the:

maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes.¹²⁶

188. Additionally, as a registrant under Section 823, Purdue was also required to monitor, report, and prevent suspicious orders of controlled substances:

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.¹²⁷

¹²⁵ See 21 U.S.C. § 823(a).

¹²⁶ 21 U.S.C. § 823(a)(1).

¹²⁷ 21 C.F.R. § 1301.74(b). See also 21 C.F.R. § 1301.02 (“Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.”); 21 C.F.R. § 1300.01 (“Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958).”)

189. Purdue, as with all the Manufacturer Defendants, had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The Manufacturer Defendants paid “chargebacks” to the Distributor Defendants. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer’s product at a price below a specified rate. After a distributor sells a manufacturer’s product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Manufacturer Defendants knew – just as the Distributor Defendants knew – the volume, frequency, and pattern of opioid orders being placed and filled. The Manufacturer Defendants built receipt of this information into the payment structure for the opioids provided to the Distributor Defendants.

190. By failing to prevent diversion and monitor, report, and stop suspicious orders of OxyContin, Purdue knowingly entered and participated in the marketing of illegal drugs in New York. Purdue is aware of the extraordinary volume of opioid prescriptions in New York in relation to other states.

191. Purdue has knowledge of the fact that such inflated prescribing levels necessarily reflect illegal prescribing and diversion of opioids. Purdue presented before the Governor’s Working Group on or about September 11, 2015. At that presentation, Purdue conceded that “[t]he abuse of prescription opioid analgesics in the US is a significant public health problem,” conceded that “OxyContin ... is subject to misuse, addiction, and criminal diversion,” and conceded that even after the creation of abuse-resistant OxyContin, “abuse by these routes [injection and nasal], as well as the oral route, is still possible.”

192. Purdue also gained knowledge of its participation in the illegal drug market in New

York through its knowledge of suspect and/or fraudulent OxyContin prescriptions and massive diversion of OxyContin based on, among other things, Purdue's own internal prescription tracking system and investigation, as well as notifications from pharmacies within New York.

193. Purdue also presented a study of OxyContin abuse in rural Kentucky which showed that oral abuse of OxyContin and Oxycodone increased following the introduction of the abuse-resistant drugs. With full knowledge of the diversion risk, Purdue flooded the market without safeguards and ignored evidence of diversion where it was plain. As detailed elsewhere in this Complaint, Purdue further made misrepresentations regarding the properties of opioids, thereby knowingly causing illegal over-prescribing and giving rise to the addicts that require diversion to feed their habits.

194. Purdue further knowingly participated in the illegal drug market in New York and elsewhere promoting the abuse-deterrent properties of OxyContin, by deliberately and knowingly downplaying addiction risks associated with opioids and through the other fraudulent conduct detailed in this Complaint. Those actions were designed to expand Purdue's market for opioids by inducing the medical community to overprescribe those drugs.

195. On information and belief, Purdue also knowingly participated in the illegal drug market in New York by supplying suspicious quantities of OxyContin to suspect physicians and pharmacies in New York, without disclosing suspicious orders as required by applicable regulations (including 21 U.S.C. § 823 and 21 C.F.R. 1301.74(b)), and otherwise circumventing Purdue's obligations under, for example, its own OxyContin Abuse and Diversion Detection Program.

196. Dr. Santiago's case is just one of many that demonstrate that Purdue did not use its database of suspected physicians to reduce OxyContin abuse, to rein in dangerous physicians, or

to stop the unlawful distribution of opioids. Instead, Purdue knowingly aided criminal activity in order to maximize its own profits.

vii. Richard Sackler Knowingly Participated in Purdue's Misdeeds by Directing Purdue Repeatedly to Distribute Drugs Unlawfully and Otherwise to Facilitate Diversion

197. The Sackler family owns Purdue (which is a private company) and has always held a majority of seats on its board. By virtue of their control, they have had the power to (and in fact did) dictate how addictive narcotics were sold in New York and elsewhere. They hired workers who helped them facilitate the creation of addicts and diversion of Purdue opioids. They fired workers whom they believed did not sell enough drugs. They controlled, ratified, and otherwise directed Purdue to commit the misconduct described in this complaint. For example, they pushed Purdue and its employees to hook more patients on opioids at increasingly higher dosages, paid themselves billions of dollars, and are also responsible for the injuries sustained by Baby Doe in the Counties.

198. Richard Sackler is one of the three brothers who founded Purdue Frederick Company in 1952. Since that time, Richard Sackler has had a controlling interest in Purdue (including the affiliated companies Purdue Pharma, Inc. and Purdue Pharma L.P. that he founded with other Sackler family members in 1990).

199. Richard Sackler took a personal interest in pushing Purdue and its employees to commit the misconduct alleged elsewhere in this complaint.

200. Richard Sackler resigned his position on Purdue's Board in 2007. However, he personally and informally continued to exert control over Purdue's operations, including personally directing Purdue employees to drive sales in New York, to contact the highest volume-most dangerous New York prescribers to urge them to prescribe more OxyContin, and otherwise

to push pills into New York communities despite knowing that it was causing widespread addiction, abuse, diversion, injury, and overdose deaths.

201. From the outset of OxyContin's launch forward, Richard Sackler pushed Purdue to market and promote OxyContin increasing volumes, regardless of the consequences and regardless of what he and Purdue actually knew about the risks and dangers of the product. At the OxyContin launch party, he announced that "the launch of OxyContin Tablets will be followed by a blizzard of prescriptions that will bury the competition. The prescription blizzard will be so deep, dense, and white"

202. In connection with OxyContin's launch in the US, Richard Sackler advocated for Purdue simultaneously to push OxyContin pills into foreign markets as a uncontrolled substance without safeguards that protect patients from addictive drugs. When a Purdue official expressed concern that this would cause the drug to be abused, Richard Sackler responded by asking how substantially this would affect Purdue's sales. In 1999, Richard Sackler became the CEO of Purdue.

203. In 2001, after receiving reports of widespread abuse and overdose deaths from OxyContin, Richard Sackler determined that Purdue should seek to shift blame onto opioids addicts and stigmatize them for their plight.

204. Richard Sackler was personally involved in pushing Purdue to engage in misconduct, including misconduct in New York. This included directing Purdue to promote OxyContin in a manner that he knew would result (and had resulted) in staggering rates of addiction, abuse, and diversion.

205. Richard Sackler knowingly sent sales representatives into New York to promote opioids to New York prescribers thousands of times, knowingly directed those sales

representatives to target the highest volume prescribers – including pill mills – to prescribe even more opioids. He knew and intended for Purdue to target the prescribers who were engaging in diversion and who were otherwise engaging in rampant over-prescription of opioids. He knew that, by doing so, he was essentially directing Purdue to create addicts and fuel the illegal drug market by blanketing New York (and small, rural communities within it) with OxyContin and other opioids. But he did not care, so long as sales volume remained high.

206. Richard Sackler micromanaged sales operations for Purdue, including efforts directed at New York prescribers. These included:

- Demanding that sales and marketing brief him on how “opioids savings cards” would drive sales, which Purdue utilized for that purpose in New York and elsewhere.
- Demanding immediate and frequent reports regarding sales strategies, and forcing the sales team to change its strategies when he found the sales targets to be too low for his liking.
- Demanding that Purdue’s sales and marketing team pursue new or different strategies to drive sales.
- Telling the sales team that he would be able to influence the Board’s decisions regarding sales and marketing strategies for OxyContin that Purdue utilized in New York and elsewhere, and in fact exerting such influence.
- Convincing the Board to expand the sales force to allow them to push OxyContin more frequently and aggressively to the highest-volume prescribers, including those in New York.
- Demanding weekly reports concerning OxyContin sales and demanding other forms of customized reports, including reports reflecting sales in New York.
- Demanding that sales representatives visit 7 or more prescribers per day in New York and elsewhere.
- Encouraging the sales force to place representatives whose sales were not high enough to be placed on performance improvement plans to drive sales back up.
- Influencing Purdue to set high quotes for the number of visits that the sales force needed to make each quarter, often over 100,000 times per quarter, including thousands of visits

on New York prescribers.

- Criticizing Purdue’s sales force for targeting “non-high potential prescribers” rather than the highest volume prescribers.
- Demanding that he be allowed to shadow sales representatives in the field to evaluate their performance, and in fact joining sales representatives in the field to promote opioids.
- Requiring Purdue’s sales to identify “corrective actions” to be taken when sales did not meet his desired targets.
- Devising strategies to avoid scrutiny by law enforcement and governmental scrutiny.

207. In April 2008, in an effort to avoid liability, Richard Sackler recommended that it was important to install a new CEO who would remain loyal to the family. He expressed that Purdue’s business posed a “dangerous concentration of risk” and that it was vital to have loyal subordinates in place to provide a legal shield. According to him, “People who shift their loyalties rapidly under stress and temptation can become a liability from the owners’ viewpoint.” Richard also proposed that the Purdue either sell the company or, in the alternative, milk profits from the business and “distribute more free cash flow” to themselves.

208. Richard Sackler knew and intended that Purdue sales representatives in New York spread misinformation concerning opioids and encourage prescribing practices that they knew would result addiction, abuse, and diversion on a wide scale. These practices included:

- a. Hiring personnel to assist Purdue in pushing pills on prescribers and patients to get them addicted to OxyContin through long-term use for chronic pain.
- b. Threatening to have Purdue fire employees who did not meet Richard’s demands.
- c. Attempting to foist blame onto patients that Purdue had convinced prescribers to hook onto its drugs.
- d. Pushing opioids for elderly patients without disclosing the higher risks.
- e. Pushing opioids for patients who had never taken them before, without disclosing the higher risks.

- f. Pushing opioids as substitutes for safer medications based on improper comparative claims.
- g. Pushing the notion of “pseudoaddiction.”
- h. Encouraging Purdue to promote OxyContin as non-addictive except as to individuals with a prior history of drug abuse.
- i. Driving sales personnel to push pills on the most dangerous and/or corrupt prescribers, and reprimanding sales personnel for taking any actions that did not drive sales higher.
- j. Encouraging Purdue to fill suspicious orders without investigation.
- k. Preventing Purdue officials from taking any actions that might decrease sales, such as implementing a legitimate suspicious order monitoring program.

209. Richard Sackler also directed Purdue to pay top prescribers money to encourage other prescribers to engage in dangerous practices in New York that he knew would create addicts and foster diversion in New York.

210. Richard Sackler’s micro-management of sales and promotional efforts after 2007 caused Purdue’s CEO to complain about Richard’s “never-ending” requests.

211. Richard Sackler paid himself large amounts of money that they he knew was derived from Purdue’s efforts to push pills onto the most dangerous prescribers and to profit from drug addiction and pill seeking behavior that they knowingly fostered.

B. Mallinckrodt

212. Mallinckrodt manufactures, markets, sells and distributes pharmaceutical drugs in Rockland County and nationwide. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

213. Among the drugs Mallinckrodt manufactures and distributes are the following: Exalgo (hydromorphone hydrochloride extended release); Roxicodone (oxycodone

hydrochloride); Xartemis XR (oxycodone hydrochloride and acetaminophen); Methadose (methadone hydrochloride); morphine sulfate extended release; fentanyl extended release; fentanyl citrate; oxycodone and acetaminophen; hydrocodone bitartrate and acetaminophen; hydromorphone hydrochloride; hydromorphone hydrochloride extended release; naltrexone hydrochloride; oxymorphone hydrochloride; methadone hydrochloride; and oxycodone hydrochloride.

214. Mallinckrodt purchased Roxicodone from Xanodyne Pharmaceuticals in 2012.¹²⁸

i. Mallinckrodt funded false publications and presentations

215. Like several of the other Manufacturer Defendants, Mallinckrodt provided substantial funding to purportedly neutral organizations which disseminated false messaging about opioids.

216. For example, until at least February 2009, Mallinckrodt provided an educational grant to Pain-Topics.org, a now-defunct website that touted itself as “a noncommercial resource for healthcare professionals, providing open access to clinical news, information, research, and education for a better understanding of evidence-based pain-management practices.”

217. Among other content, the website included a handout titled “Oxycodone Safety Handout for Patients,” which advised practitioners that: “Patients’ fears of opioid addiction should be dispelled.”¹²⁹ The handout included several false and misleading statements concerning the risk of addiction associated with prescription opioids:

¹²⁸ *Mallinckrodt Announces Agreement with Xanodyne to Purchase Roxicodone*, Bus. Wire (Aug. 23, 2012). Available at: <http://www.businesswire.com/news/home/20120823005209/en/Mallinckrodt-Announces-Agreement-Xanodyne-Purchase-Roxicodone%C2%AE>.

¹²⁹ Lee A. Kral & Stewart B. Leavitt, *Oxycodone Safety Handout for Patients*, Pain-Topics.Org (June 2007). Available at: <http://paincommunity.org/blog/wp-content/uploads/Oxycodone/Handout.pdf>.

Will you become dependent on or addicted to oxycodone?

- After a while, oxycodone causes physical dependence. That is, if you suddenly stop the medication you may experience uncomfortable withdrawal symptoms, such as diarrhea, body aches, weakness, restlessness, anxiety, loss of appetite, and other ill feelings. These may take several days to develop.
- This is not the same as addiction, a disease involving craving for the drug, loss of control over taking it or compulsive use, and using it despite harm. Addiction to oxycodone in persons without a recent history of alcohol or drug problems is rare.¹³⁰

218. Another document available on the website, “Commonsense Oxycodone Prescribing & Safety,” falsely suggests that generic oxycodone is less prone to abuse and diversion than branded oxycodone: “Anecdotally, it has been observed that generic versions of popularly abused opioids usually are less appealing; persons buying drugs for illicit purposes prefer brand names because they are more recognizable and the generics have a lower value ‘on the street,’ which also makes them less alluring for drug dealers.”¹³¹

219. In November 2016, Mallinckrodt paid Dr. Scott Gottlieb (“Gottlieb”), the new commissioner of the FDA, \$22,500 for a speech in London, shortly after the U.S. presidential election.¹³² Gottlieb has also received money from the Healthcare Distribution Alliance, an industry-funded organization that pushes the agenda of large pharmaceutical wholesalers, and he has often criticized efforts aimed at regulating the pharmaceutical opioid market.¹³³

¹³⁰ *Id.*

¹³¹ Lee A. Kral, *Commonsense Oxycodone Prescribing & Safety*, Pain-Topics.org (June 2007). Available at: <http://paincommunity.org/blog/wp-content/uploads/OxycodoneRxSafety.pdf>.

¹³² Lee Fang, *Donald Trump’s Pick to Oversee Big Pharma Is Addicted to Opioid-Industry Cash*, Intercept (Apr. 4, 2017, 2:15 PM). Available at: <https://theintercept.com/2017/04/04/scott-gottlieb-opioid/>.

¹³³ *Id.*

ii. Mallinckrodt failed to prevent diversion and to monitor, report, and stop suspicious orders of its prescription opioid products as required

220. In its July 2017 settlement agreement with Mallinckrodt, the DEA explained that:

Through its investigation, the government learned that manufacturers of pharmaceuticals offer discounts, known as “chargebacks,” based on sales to certain downstream customers. Distributors provide information on the downstream customer purchases to obtain the discount. The groundbreaking nature of the settlement involves requiring a manufacturer to utilize chargeback and similar data to monitor and report to DEA suspicious sales of its oxycodone at the next level in the supply chain, typically sales from distributors to independent and small chain pharmacy and pain clinic customers.¹³⁴

221. The 2017 settlement agreement confirms that, “[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to the DEA.”¹³⁵ The settlement agreement further provides that, “Mallinckrodt had an obligation to act only as authorized by its DEA registration including the responsibility to distribute its drugs legally through legitimate channels,” which Mallinckrodt allegedly did not do.¹³⁶

222. The 2017 settlement agreement details the allegations regarding Mallinckrodt’s failures to fulfill its legal duties as an opioid manufacturer as an opioid manufacturer to prevent diversion.¹³⁷

223. By failing to prevent diversion and monitor, report, and stop suspicious orders of its prescription opioid products, Mallinckrodt knowingly entered and participated in the marketing of illegal drugs in New York. Mallinckrodt is aware of the extraordinary volume of opioid

¹³⁴ Mallinckrodt MOA at 9.

¹³⁵ *Id.* at 1.

¹³⁶ *Id.*

¹³⁷ *Id.* at 2-3.

prescriptions in New York in relation to other states. Mallinckrodt knew that such inflated prescribing necessarily reflects improper prescribing and diversion of opioids, including Mallinckrodt's products.

224. Mallinckrodt further knowingly participated in the illegal drug market in New York and elsewhere by knowingly shirking its responsibility to detect and investigate suspicious orders, for which it was cited by the DEA, by deliberately and knowingly downplaying addiction risks associated with opioids and through the other knowing, fraudulent actions detailed in this Complaint. Those actions were designed to expand Mallinckrodt's market for opioids by inducing the medical community to overprescribe those drugs.

225. On information and belief, Mallinckrodt also knowingly participated in the illegal drug market in the in New York by supplying suspicious quantities of its products to suspect physicians and pharmacies in New York, without disclosing suspicious orders as required by applicable regulations.

C. Cephalon

226. Cephalon manufactures, markets, sells and distributes pharmaceutical drugs in Rockland County and nationwide.

227. Among the drugs Janssen manufactures and distributes are the following: Actiq (fentanyl citrate); Fentora (fentanyl buccal); and oxycodone hydrochloride.

228. Actiq is designed to resemble a lollipop and is meant to be sucked on at the onset of intense BTP in cancer patients. It delivers fentanyl citrate, a powerful opioid agonist that is 80 times stronger than morphine,¹³⁸ rapidly into a patient's bloodstream through the oral membranes.

¹³⁸ John Carreyrou, *Narcotic "Lollipop" Becomes Big Seller Despite FDA Curbs*, Wall St. J. (Nov. 3, 2006). Available at: <https://www.opiates.com/media/narcotic-lollipop-becomes-big-seller-despite-fda-curbs/> (last visited Jan. 2, 2018).

Because it is absorbed through those membranes, it passes directly into circulation without having to go through the liver or stomach, thereby providing faster relief.

229. In November 1998, the FDA approved Actiq for only a very narrow group of people – cancer patients “with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.”¹³⁹

230. Understanding the risks of introducing such an intense opioid analgesic to the market, the FDA provided approval of Actiq “**ONLY** for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.”¹⁴⁰ Further, the FDA explicitly stated that Actiq “**must not** be used in opioid non-tolerant patients,” was contraindicated for the management of acute or postoperative pain, could be deadly to children and was “intended to be used only in the care of opioid-tolerant cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.”

231. The FDA also required that Actiq be provided only in compliance with a strict risk-management program that explicitly limited the drug’s direct marketing to the approved target audiences, defined as oncologists, pain specialists, their nurses and office staff.

232. In October 2000, Cephalon acquired the worldwide product rights to Actiq and began marketing and selling Actiq in the United States.

233. Cephalon purchased the rights to Fentora, an even faster-acting tablet formulation of fentanyl, from Cima Labs, and submitted a new drug application to the FDA in August 2005. In September 2006, Cephalon received FDA approval to sell this faster-acting version of Actiq;

¹³⁹ 1998 FDA Label.

¹⁴⁰ NDA 20-747 Letter from Cynthia McCormick, Center for Drug Evaluation and Research, to Patricia J. Richards, Anesta Corporation.

but once again, concerned about the power and risks inherent to fentanyl, the FDA limited Fentora's approval to the treatment of BTP in cancer patients who were already tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Cephalon began marketing and selling Fentora in October 2006.

i. Cephalon aggressively marketed a cancer drug to non-cancer treating physicians

234. Due to the FDA's restrictions, Actiq's consumer base was limited, as was its potential for growing revenue. In order to increase its revenue and market share, Cephalon needed to find a broader audience and thus began marketing its lollipop to treat headaches, back pain, sports injuries and other chronic non-cancer pain, targeting non-oncology practices, including, but not limited to, pain doctors, general practitioners, migraine clinics, anesthesiologists and sports clinics. It did so in violation of applicable regulations prohibiting the marketing of medications for off-label use and in direct contravention of the FDA's strict instructions that Actiq be prescribed only to terminal cancer patients and by oncologists and pain management doctors experienced in treating cancer pain.

235. According to "[d]ata gathered from a network of doctors by research firm ImpactRx between June 2005 and October 2006" ("ImpactRx Survey"), Cephalon sales representatives' visits to non-oncologists to pitch Actiq increased six-fold between 2002 and 2005. Cephalon representatives would reportedly visit non-oncologists monthly, providing up to 60 or 70 coupons (each coupon was good for six free Actiq lozenges) and encouraging prescribers to try Actiq on their non-cancer patients.¹⁴¹

236. Cephalon's efforts paid off. In 2000, Actiq generated \$15 million in sales.¹⁴² By

¹⁴¹ Carreyrou, *Narcotic Lollipop*.

¹⁴² *Id.*

2002, it attributed a 92% increase in Actiq sales to “a dedicated sales force for ACTIQ” and “ongoing changes to [its] marketing approach including hiring additional sales representatives and targeting our marketing efforts to pain specialists.”¹⁴³ By 2005, Actiq’s sales total had jumped to \$412 million, making it (a drug approved for only a narrow customer base) Cephalon’s second-bestselling drug. By the end of 2006, Actiq’s sales had exceeded \$500 million.¹⁴⁴

237. Only 1% of the 187,076 prescriptions for Actiq filled at retail pharmacies during the first six months of 2006 were prescribed by oncologists. Results of the ImpactRx Survey suggested that “more than 80 percent of patients who use[d] the drug don’t have cancer.”¹⁴⁵

ii. Government investigations found Cephalon falsely marketed Actiq for off-label uses

238. Beginning in or about 2003, former Cephalon employees filed four whistleblower lawsuits claiming the company had wrongfully marketed Actiq for unapproved, off-label uses. On September 29, 2008, Cephalon finalized and entered into a corporate integrity agreement with the Office of the Inspector General of HHS and agreed to pay \$425 million in civil and criminal penalties for its off-label marketing of Actiq and two other drugs (Gabitril and Provigil).

239. According to a DOJ press release, Cephalon trained sales representatives to disregard restrictions of the FDA-approved label, employed sales representatives and healthcare professionals to speak to physicians about off-label uses of the three drugs and funded CME to promote off-label uses. Specifically, the DOJ stated:

From 2001 through at least 2006, Cephalon was allegedly promoting [Actiq] for non-cancer patients to use for such maladies as migraines, sickle-cell pain crises, injuries, and in anticipation of changing wound dressings or radiation therapy. Cephalon also

¹⁴³ Cephalon, Inc. Annual Report (Form 10-K) at 28 (Mar. 31, 2003).

¹⁴⁴ Carreyrou, *Narcotic Lollipop*.

¹⁴⁵ *Id.*

promoted Actiq for use in patients who were not yet opioid-tolerant, and for whom it could have life-threatening results.¹⁴⁶

240. Then-acting U.S. Attorney Laurie Magid commented on the dangers of Cephalon's unlawful practices:

This company subverted the very process put in place to protect the public from harm, and put patients' health at risk for nothing more than boosting its bottom line. People have an absolute right to their doctors' best medical judgment. They need to know the recommendations a doctor makes are not influenced by sales tactics designed to convince the doctor that the drug being prescribed is safe for uses beyond what the FDA has approved.¹⁴⁷

241. Upon information and belief, documents uncovered in the government's investigations confirm that Cephalon directly targeted non-oncology practices and pushed its sales representatives to market Actiq for off-label use. For instance, the government's investigations confirmed:

- Cephalon instructed its sales representatives to ask non-cancer doctors whether they have the potential to treat cancer pain. Even if the doctor answered "no," a decision tree provided by Cephalon instructed the sales representatives to give these physicians free Actiq coupons;
- Cephalon targeted neurologists in order to encourage them to prescribe Actiq to patients with migraine headaches;
- Cephalon sales representatives utilized the assistance of outside pain management specialists when visiting non-cancer physicians to pitch Actiq. The pain management specialist would falsely inform the physician that Actiq does not cause patients to experience a "high" and carries a low risk of diversion toward recreational use;
- Cephalon set sales quotas for its sales and marketing representatives that could not possibly have been met solely by promoting Actiq for its FDA-

¹⁴⁶ Press Release, U.S. Department of Justice, Pharmaceutical Company Cephalon To Pay \$425 Million For Off-Label Drug Marketing (Sept. 29, 2008). Available at: <https://www.justice.gov/archive/usao/pae/News/2008/sep/cephalonrelease.pdf>.

¹⁴⁷ *Id.*

approved indication;

- Cephalon promoted the use of higher doses of Actiq than patients required by encouraging prescriptions of the drug to include larger-than-necessary numbers of lozenges with unnecessarily high doses of fentanyl; and
- Cephalon promoted Actiq for off-label use by funding and controlling CME seminars that promoted and misrepresented the efficacy of the drug for off-label uses such as treating migraine headaches and for patients not already opioid-tolerant.¹⁴⁸

242. Still, the letters, the FDA's safety alert, DOJ and state investigations and the massive settlement seemed to have had little impact on Cephalon as it continued its deceptive marketing strategy for both Actiq and Fentora.

iii. Cephalon focused on non-cancer treating physicians in falsely marketing Fentora

243. From the time it first introduced Fentora to the market in October 2006, Cephalon targeted non-cancer doctors, falsely represented Fentora as a safe, effective off-label treatment for non-cancer pain and continued its disinformation campaign about the safety and non-addictiveness of Fentora specifically and opioids generally. In fact, Cephalon targeted the same pain specialists and non-oncologists that it had targeted with its off-label marketing of Actiq, simply substituting Fentora.

244. During an investor earnings call shortly after Fentora's launch, Cephalon's chief executive officer ("CEO") described the "opportunity" presented by the use of Fentora for non-cancer pain:

The other opportunity of course is the prospect for FENTORA outside of cancer pain, in indications such as breakthrough lower back pain and breakthrough neuropathic pain.

¹⁴⁸ John Carreyrou, *Cephalon Used Improper Tactics to Sell Drug, Probe Finds*, Wall St. J., Nov. 21, 2006, at B1 (hereinafter "Carreyrou, *Cephalon Used Improper Tactics*").

Of all the patients taking chronic opioids, 32% of them take that medication to treat back pain, and 30% of them are taking their opioids to treat neuropathic pain. In contrast only 12% are taking them to treat cancer pain, 12%.

We know from our own studies that breakthrough pain episodes experienced by these non-cancer sufferers respond very well to FENTORA. And for all these reasons, we are tremendously excited about the significant impact FENTORA can have on patient health and wellbeing and the exciting growth potential that it has for Cephalon.

In summary, we have had a strong launch of FENTORA and continue to grow the product aggressively. Today, that growth is coming from the physicians and patient types that we have identified through our efforts in the field over the last seven years. In the future, with new and broader indications and a much bigger field force presence, the opportunity that FENTORA represents is enormous.¹⁴⁹

iv. The FDA warned Cephalon regarding its false and off-label marketing of Fentora

245. On September 27, 2007, the FDA issued a public health advisory to address numerous reports that patients who did not have cancer or were not opioid tolerant had been prescribed Fentora, and death or life-threatening side effects had resulted. The FDA warned: “Fentora should not be used to treat any type of short-term pain.”¹⁵⁰

246. Nevertheless, in 2008, Cephalon pushed forward to expand the target base for Fentora and filed a supplemental drug application requesting FDA approval of Fentora for the

¹⁴⁹ Seeking Alpha, Transcript of Q1 2007 Cephalon, Inc. Earnings Conference Call, at 6-7 (May 1, 2007). Available at: <http://seekingalpha.com/article/34163-cephalon-q1-2007-earnings-call-transcript?all=true&find=Q1%2B2007%2BCephalon%2BMay%2B1%2C%2B2007>.

¹⁵⁰ Press Release, U.S. Food & Drug Administration, Public Health Advisory: Important Information for the Safe Use of Fentora (fentanyl buccal tablets) (Sept. 26, 2007).

treatment of non-cancer BTP. In the application and supporting presentations to the FDA, Cephalon admitted both that it knew the drug was heavily prescribed for off-label use and that the drug's safety for such use had never been clinically evaluated.¹⁵¹ An FDA advisory committee lamented that Fentora's existing risk management program was ineffective and stated that Cephalon would have to institute a risk evaluation and mitigation strategy for the drug before the FDA would consider broader label indications. In response, Cephalon revised Fentora's label and medication guide to add strengthened warnings.

247. But in 2009, the FDA once again informed Cephalon that the risk management program was not sufficient to ensure the safe use of Fentora for already approved indications.

248. On March 26, 2009, the FDA warned Cephalon against its misleading advertising of Fentora ("Warning Letter"). The Warning Letter described a Fentora Internet advertisement as misleading because it purported to broaden "the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora . . . when this is not the case." Rather, Fentora was only indicated for those who were already opioid tolerant. It further criticized Cephalon's other direct Fentora advertisements because they did not disclose the risks associated with the drug.

249. Flagrantly disregarding the FDA's refusal to approve Fentora for non-cancer BTP and its warning against marketing the drug for the same, Cephalon continued to use the same sales tactics to push Fentora as it did with Actiq.

250. For example, on January 13, 2012, Cephalon published an insert in *Pharmacy Times* titled "An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA

¹⁵¹ *FENTORA (fentanyl buccal tablet) CII, Joint Meeting of Anesthetic and Life Support Drugs and Drug Safety and Risk Management Advisory Committee, U.S. Food & Drug Administration (May 6, 2008).*

(Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate).” Despite the repeated warnings of the dangers associated with the use of the drugs beyond their limited indication, as detailed above, the first sentence of the insert states: “It is well recognized that the judicious use of opioids can facilitate effective and safe management of chronic pain.”¹⁵²

v. Cephalon funded false publications and presentations

251. In addition to its direct marketing, Cephalon indirectly marketed through third parties to change the way doctors viewed and prescribed opioids – disseminating the unproven and deceptive messages that opioids were safe for the treatment of chronic, long-term pain, that they were non-addictive and that they were woefully under-prescribed to the detriment of patients who were needlessly suffering. It did so by sponsoring pro-opioid front groups, misleading prescription guidelines, articles and CMEs, and it paid physicians thousands of dollars every year to publicly opine that opioids were safe, effective and non-addictive for a wide variety of uses.

252. Cephalon sponsored numerous CMEs, which were made widely available through organizations like Medscape, LLC (“Medscape”) and which disseminated false and misleading information to physicians in Rockland County and across the country.

253. For example, a 2003 Cephalon-sponsored CME presentation titled “Pharmacologic Management of Breakthrough or Incident Pain,” posted on Medscape in February 2003, teaches:

[C]hronic pain is often undertreated, particularly in the noncancer patient population. . . . The continued stigmatization of opioids and their prescription, coupled with often unfounded and self-imposed physician fear of dealing with the highly regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest

¹⁵² *An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Bucall Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate)*, Pharmacy Times (Jan. 13, 2012).

*in substance abuse. In fact, patient fears of developing substance abuse behaviors such as addiction often lead to undertreatment of pain. The concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse.*¹⁵³

254. Another Cephalon-sponsored CME presentation titled “Breakthrough Pain: Treatment Rationale with Opioids” was available on Medscape starting September 16, 2003 and was given by a self-professed pain management doctor who “previously operated back, complex pain syndromes, the neuropathies, and interstitial cystitis.” He describes the pain process as a non-time-dependent continuum that requires a balanced analgesia approach using “targeted pharmacotherapeutics to affect multiple points in the pain-signaling pathway.”¹⁵⁴ The doctor lists fentanyl as one of the most effective opioids available for treating BTP, describing its use as an expected and normal part of the pain management process. Nowhere in the CME is cancer or cancer-related pain even mentioned.

255. In 2006, Cephalon sponsored a review of scientific literature to create additional fentanyl-specific dosing guidelines titled “Evidence-Based Oral Transmucosal Fentanyl Citrate (OTFC®) Dosing Guidelines.”¹⁵⁵ The article purports to review the evidence for dosing and efficacy of oral transmucosal fentanyl citrate in the management of pain and produce dosing guidelines in both cancer and non-cancer patients. In pertinent part, it states:

Oral transmucosal fentanyl citrate has a proven benefit in treating

¹⁵³ Michael J. Brennan, *et al.*, *Pharmacologic Management of Breakthrough or Incident Pain*, Medscape, <http://www.medscape.org/viewarticle/449803> (last visited Jan. 2, 2018).

¹⁵⁴ Daniel S. Bennett, *Breakthrough Pain: Treatment Rationale With Opioids*, Medscape, <http://www.medscape.org/viewarticle/461612> (last visited Jan. 2, 2018).

¹⁵⁵ Gerald M. Aronoff, *et al.*, *Evidence-Based Oral Transmucosal Fentanyl Citrate (OTFC) Dosing Guidelines*, 6(4) Pain Med. 305-14 (Aug. 2005).

cancer-associated breakthrough pain in opioid-tolerant patients with cancer, which is the Food and Drug Administration (FDA)-approved indication for Actiq. ***Pain medicine physicians have also used OTFC successfully to provide rapid pain relief in moderate to severe noncancer pain in both opioid-tolerant and opioid-nontolerant patients.***¹⁵⁶

256. Deeper into the article, the authors attempt to assuage doctors' concerns regarding possible overdose and respiratory distress in non-cancer patients by arguing "[t]here is no evidence that opioid safety and efficacy differs in opioid-tolerant patients with chronic noncancer pain."

Regarding the use of fentanyl to treat non-opioid-tolerant patients, the article's authors stated:

Alternatively, ***OTFC might also be used cautiously and safely for acute pain experienced by patients who are not opioid tolerant. Parenteral opioids are routinely used for acute pain in patients who are not opioid tolerant.*** Examples include episodic pain (*i.e.*, refractory migraine pain, recurrent renal calculi, etc.) and acute pain that follows surgery, trauma, or painful procedures (burn dressing change, bone marrow aspiration, lumbar puncture). Assuming that clinical experience with IV morphine in patients who are not opioid tolerant can be extrapolated, OTFC should be safe and efficacious in such settings as well.¹⁵⁷

257. Through its sponsorship of the FSMB's "Responsible Opioid Prescribing: A Physician's Guide," Cephalon continued to encourage the prescribing of opioid medication to "reverse . . . and improve" patient function, attributing patients' displays of traditional drug-seeking behaviors as merely "pseudoaddiction."

258. Cephalon also disseminated its false messaging through speakers' bureaus and publications. For example, at an AAPM annual meeting held February 22 through 25, 2006, Cephalon sponsored a presentation by Webster and others titled "Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: Interim safety

¹⁵⁶ *Id.*

¹⁵⁷ *Id.*

results.” The presentation’s agenda description states: “Most patients with chronic pain experience episodes of breakthrough pain (BTP), yet no currently available pharmacologic agent is ideal for its treatment.” The presentation purports to cover a study analyzing the safety of a new form of fentanyl buccal tablets in the chronic pain setting and promises to show the “[i]nterim results of this study suggest that FEBT is safe and well-tolerated in patients with chronic pain and BTP.”

259. Cephalon sponsored another CME written by Webster and M. Beth Dove titled “Optimizing Opioid Treatment for Breakthrough Pain” and offered on Medscape from September 28, 2007 through December 15, 2008. The CME teaches that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating BTP than pure opioid analgesics because of dose limitations on the non-opioid component.¹⁵⁸

260. Fine authored a Cephalon-sponsored CME titled “Opioid-Based Management of Persistent and Breakthrough Pain,” with Drs. Christine A. Miaskowski and Michael J. Brennan. Cephalon paid to have this CME published in a “Special Report” supplement of the journal *Pain Medicine News* in 2009.¹⁵⁹ The CME targeted a wide variety of non-oncologist healthcare providers who treat patients with chronic pain with the objective of educating “health care professionals about a semi-structured approach to the opioid-based management of persistent and breakthrough pain,” including the use of fentanyl. The CME purports to analyze the “combination of evidence- and case-based discussions” and ultimately concludes:

Chronic pain is a debilitating biopsychosocial condition prevalent in both cancer and noncancer pain populations. . . . Opioids have an

¹⁵⁸ Lynn Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, Medscape, http://www.medscape.org/viewarticle/563417_6 (last visited Jan. 2, 2018).

¹⁵⁹ Perry G. Fine, *et al.*, *Opioid-Based Management of Persistent and Breakthrough Pain*, Special Report (2009), <https://www.yumpu.com/en/document/view/11409251/opioid-based-management-of-persistent-and-breakthrough-pain/9>.

established role in pain related to cancer and other advanced medical illnesses, as well as an increasing contribution to the long-term treatment of carefully selected and monitored patients with certain [chronic noncancer pain] conditions. ***All individuals with chronic, moderate to severe pain associated with functional impairment should be considered for a trial of opioid therapy, although not all of them will be selected.***¹⁶⁰

261. Along with Purdue, Cephalon sponsored APF's guide, which warned against the purported ***under***-prescribing of opioids, taught that addiction is ***rare*** and suggested that opioids have "***no ceiling dose***" and are therefore the most appropriate treatment for severe pain.

262. A summary of the February 12-16, 2008 AAPM annual meeting reinforced the message, promoted both by the AAPM and the APS, that "the undertreatment of pain is unjustified." It continues:

Pain management is a fundamental human right in all patients not only with acute postoperative pain but also ***in patients suffering from chronic pain***. Treating the underlying cause of pain does not usually treat all of the ongoing pain. Minimal pathology with maximum dysfunction remains the enigma of chronic pain. Chronic pain is only recently being explored as a complex condition that requires individual treatment and a multidisciplinary approach. It is considered to be a disease entity.¹⁶¹

263. In the March 2007 article titled "Impact of Breakthrough Pain on Quality of Life in Patients with Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment with Oral Transmucosal Fentanyl Citrate,"¹⁶² published in the nationally circulated journal *Pain Medicine*, physicians paid by Cephalon (including Webster) described the results of a Cephalon-sponsored

¹⁶⁰ *Id.*

¹⁶¹ Mohamed A. Elkersh & Zahid H. Bajwa, *Highlights From the American Academy of Pain Medicine 24th Annual Meeting*, 2(1) *Advances in Pain Management* 50-52 (2008).

¹⁶² Donald R. Taylor, *et al.*, *Impact of Breakthrough Pain on Quality of Life in Patients With Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment With Oral Transmucosal Fentanyl Citrate (OTFC, ACTIQ)*, 8(3) *Pain Med.* 281-88 (Mar. 2007).

study seeking to expand the definition of BTP to the chronic, non-cancer setting. The authors stated that the “OTFC has been shown to relieve BTP more rapidly than conventional oral, normal-release, or ‘short acting’ opioids” and that “[t]he purpose of [the] study was to provide a qualitative evaluation of the effect of BTP on the [quality of life] of noncancer pain patients.”¹⁶³ The number-one-diagnosed source of chronic pain in the patients studied was back pain (44%), followed by musculoskeletal pain (12%) and head pain (7%). The article cites Portenoy and recommends fentanyl for non-cancer BTP patients:

In summary, BTP appears to be a clinically important condition in patients with ***chronic noncancer pain*** and is associated with an adverse impact on QoL. This qualitative study on the negative impact of BTP ***and the potential benefits of BTP-specific therapy*** suggests several domains that may be helpful in developing BTP-specific, QoL assessment tools.¹⁶⁴

264. Cephalon also sponsored, through an educational grant, the regularly published journal *Advances in Pain Management*. In a single 2008 issue of the journal, there are numerous articles from Portenoy, Dr. Steven Passik (“Passik”), Dr. Kenneth L. Kirsh (“Kirsh”) and Webster, all advancing the safety and efficacy of opioids. In an article titled “Screening and Stratification Methods to Minimize Opioid Abuse in Cancer Patients,” Webster expresses disdain for the prior 20 years of opioid phobia.

265. In another article from the same issue, “Appropriate Prescribing of Opioids and Associated Risk Minimization,” Passik and Kirsh state: “[c]hronic pain, currently experienced by approximately 75 million Americans, is becoming one of the biggest public health problems in the US.” They assert that addiction is rare, that “[m]ost pain specialists have prescribed opioids for

¹⁶³ *Id.*

¹⁶⁴ *Id.*

long periods of time with success demonstrated by an improvement in function” and that then-recent work had shown “that opioids do have efficacy for subsets of patients who can remain on them long term and have very little risk of addiction.”¹⁶⁵

266. In November 2010, Fine and others published an article presenting the results of another Cephalon-sponsored study titled “Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study.”¹⁶⁶ In that article, Fine explained that the 18-month “open-label” study “assessed the safety and tolerability of FBT [Fentora] for the [long-term] treatment of BTP in a large cohort . . . of opioid-tolerant patients receiving around-the-clock . . . opioids for noncancer pain.” The article acknowledges that: (a) “[t]here has been a steady increase in the use of opioids for the management of chronic noncancer pain over the past two decades”; (b) the “widespread acceptance” had led to the publishing of practice guidelines “to provide evidence- and consensus-based recommendations for the optimal use of opioids in the management of chronic pain”; and (c) those guidelines lacked “data assessing the long-term benefits and harms of opioid therapy for chronic pain.”¹⁶⁷

267. They conclude: “[T]he safety and tolerability profile of FBT in this study was generally typical of a potent opioid. The [adverse events] observed were, in most cases, predictable, manageable, and tolerable.” They also conclude that the number of abuse-related events was “small.”¹⁶⁸

¹⁶⁵ Steven D. Passik & Kenneth L. Kirsh, *Appropriate Prescribing of Opioids and Associated Risk Minimization*, 2(1) *Advances in Pain Management* 9-16 (2008).

¹⁶⁶ Perry G. Fine, *et al.*, *Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study*, 40(5) *J. Pain & Symptom Management* 747-60 (Nov. 2010).

¹⁶⁷ *Id.*

¹⁶⁸ *Id.*

268. From 2000 forward, Cephalon has paid doctors nationwide millions of dollars for programs relating to its opioids, many of whom were not oncologists and did not treat cancer pain. These doctors included Portenoy, Webster, Fine, Passik, Kirsh, Landy and others.

269. Cephalon's payments to doctors have resulted in studies that support its sales but, on closer examination, are biased or irreparably flawed. For instance, on information and belief, the governmental whistleblower investigation into Actiq revealed that two studies touted by Cephalon had tested fewer than 28 patients and had no control group whatsoever.¹⁶⁹ A 2012 article evaluating the then-current status of transmucosal fentanyl tablet formulations for the treatment of BTP in cancer patients noted that clinical trials to date used varying criteria, that "the approaches taken . . . [did] not uniformly reflect clinical practice" and that "the studies ha[d] been sponsored by the manufacturer and so ha[d] potential for bias."¹⁷⁰

vi. Cephalon failed to prevent diversion and to monitor, report, and stop suspicious orders of its prescription opioid products as required

270. The federal CSA imposes on all "registrants" the obligation to design and operate a system to disclose to the registrant suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."¹⁷¹

271. Cephalon is a "registrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in

¹⁶⁹ Carreyrou, *Cephalon Used Improper Tactics*.

¹⁷⁰ Eric Prommer & Brandy Fleck, *Fentanyl transmucosal tablets: current status in the management of cancer-related breakthrough pain*, 2012(6) Patient Preference and Adherence 465-75 (June 25, 2012).

¹⁷¹ 21 C.F.R. §1301.74(b).

turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

272. Cephalon failed to design and operate a system to disclose suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders.

273. By failing to prevent diversion and monitor, report, and stop suspicious orders of its prescription opioid products, Cephalon knowingly entered and participated in the marketing of illegal drugs in New York. Cephalon knew that such inflated prescribing necessarily reflects improper prescribing and diversion of opioids, including Mallinckrodt's products.

274. Cephalon further knowingly participated in the illegal drug market in New York and elsewhere by knowingly shirking its responsibility to detect and investigate suspicious orders, for which it was cited by the DEA, by deliberately and knowingly downplaying addiction risks associated with opioids and through the other knowing, fraudulent actions detailed in this Complaint. Those actions were designed to expand Cephalon's market for opioids by inducing the medical community to overprescribe those drugs.

275. On information and belief, Cephalon also knowingly participated in the illegal drug market in the in New York by supplying suspicious quantities of its products to suspect physicians and pharmacies in New York, without disclosing suspicious orders as required by applicable regulations.

D. Janssen

276. Janssen manufactures, markets, sells and distributes pharmaceutical drugs in Rockland County and nationwide.

277. Among the drugs Janssen manufactures and distributes are the following: Duragesic (fentanyl); Nucynta (tapentadol hydrochloride); and Nucynta ER (tapentadol

hydrochloride extended release).

278. Janssen introduced Duragesic in 1990. It is indicated for the “management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.” Janssen also markets Nucynta, which was first approved by the FDA in 2008, formulated in tablet form and in an oral solution and indicated for the “relief of moderate to severe acute pain in patients 18 years of age or older.” Additionally, Janssen markets Nucynta ER, which was first approved by the FDA in 2011 in tablet form. Initially, it was indicated for the “management of . . . pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.” This pain indication was later altered to “management of moderate to severe chronic pain in adults” and “neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults.” Janssen sold Nucynta and Nucynta ER to Depomed in 2015 for \$1.05 billion.

i. The FDA warned Janssen regarding its false messaging

279. On February 15, 2000, the FDA sent Janssen a letter concerning the alleged dissemination of “homemade” promotional pieces that promoted Duragesic in violation of the Federal Food, Drug, and Cosmetic Act. In a subsequent letter dated March 30, 2000, the FDA explained that the “homemade” promotional pieces were “false or misleading because they contain misrepresentations of safety information, broaden Duragesic’s indication, contain unsubstantiated claims, and lack fair balance.”

280. The March 30, 2000 letter identified specific violations, including misrepresentations that Duragesic had a low potential for abuse:

You present the claim, “Low abuse potential!” This claim suggests that Duragesic has less potential for abuse than other currently

available opioids. However, this claim has not been demonstrated by substantial evidence. Furthermore, this claim is contradictory to information in the approved product labeling (PI) that states, “Fentanyl is a Schedule II controlled substance and can produce drug dependence similar to that produced by morphine.” Therefore, this claim is false or misleading.¹⁷²

281. The March 30, 2000 letter also stated that the promotional materials represented that Duragesic was “more useful in a broader range of conditions or patients than has been demonstrated by substantial evidence.” Specifically, the FDA stated that Janssen was marketing Duragesic for indications beyond the treatment of chronic pain that cannot otherwise be managed, for which it was approved:

You present the claim, “It’s not just for end stage cancer anymore!” This claim suggests that Duragesic can be used for any type of pain management. However, the PI for Duragesic states, “Duragesic (fentanyl transdermal system) is indicated in the management of chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by lesser means” Therefore, the suggestion that Duragesic can be used for any type of pain management promotes Duragesic[] for a much broader use than is recommended in the PI, and thus, is misleading. In addition, the suggestion that Duragesic can be used to treat any kind of pain is contradictory to the boxed warning in the PI. Specifically, the PI states: “BECAUSE SERIOUS OR LIFE-THREATENING HYPOVENTILATION COULD OCCUR, DURAGESIC® (FENTANYL TRANSDERMAL SYSTEM) IS CONTRAINDICATED: ... In the management of acute or post-operative pain, including use in out-patient surgeries”¹⁷³

282. The March 30, 2000 letter also stated Janssen failed to adequately present “contraindications, warnings, precautions, and side effects with a prominence and readability reasonably comparable to the presentation of information relating to the effectiveness of the

¹⁷² NDA 19-813 Letter from Spencer Salis, U.S. Food & Drug Administration, to Cynthia Chianese, Janssen Pharmaceutica, at 2 (Mar. 30, 2000).

¹⁷³ *Id.* at 2-3.

product”:

Although this piece contains numerous claims for the efficacy and safety of Duragesic, *you have not presented any risk information* concerning the boxed warnings, contraindications, warnings, precautions, or side effects associated with Duragesic’s use Therefore, this promotional piece is lacking in fair balance, or otherwise misleading, because it fails to address important risks and restrictions associated with Duragesic therapy.¹⁷⁴

283. On September 2, 2004, the U.S. Department of Health and Human Services (“HHS”) sent Janssen a warning letter concerning Duragesic due to “false or misleading claims about the abuse potential and other risks of the drug, and . . . unsubstantiated effectiveness claims for Duragesic,” including, specifically, “suggesting that Duragesic has a lower potential for abuse compared to other opioid products.”

284. The September 2, 2004 letter warned Janssen regarding its claims that Duragesic had a low reported rate of mentions in the Drug Abuse Warning Network (“DAWN”) as compared to other opioids. The letter stated that the claim was false or misleading because the claim was not based on substantial data and because the lower rate of mentions was likely attributable to Duragesic’s lower frequency of use compared to other opioids listed in DAWN:

The file card presents the prominent claim, “Low reported rate of mentions in DAWN data,” along with Drug Abuse Warning Network (DAWN) data comparing the number of mentions for Fentanyl/combinations (710 mentions) to other listed opioid products, including Hydrocodone/combinations (21,567 mentions), Oxycodone/combinations (18,409 mentions), and Methadone (10,725 mentions). The file card thus suggests that Duragesic is less abused than other opioid drugs.

This is false or misleading for two reasons. First, we are not aware of substantial evidence or substantial clinical experience to support this comparative claim. The DAWN data cannot provide the basis

¹⁷⁴ *Id.* at 3 (emphasis in original).

for a valid comparison among these products. As you know, DAWN is not a clinical trial database. Instead, it is a national public health surveillance system that monitors drug-related emergency department visits and deaths. If you have other data demonstrating that Duragesic is less abused, please submit them.

Second, Duragesic is not as widely prescribed as other opioid products. As a result, the relatively lower number of mentions could be attributed to the lower frequency of use, and not to a lower incidence of abuse. The file card fails to disclose this information.¹⁷⁵

285. The September 2, 2004 letter also details a series of unsubstantiated, false or misleading claims regarding Duragesic's effectiveness. The letter concluded that various claims made by Janssen were insufficiently supported.¹⁷⁶

286. In addition, the September 2, 2004 letter identifies "outcome claims [that] are misleading because they imply that patients will experience improved social or physical functioning or improved work productivity when using Duragesic." The claims include "'1,360 loaves . . . and counting,' '[w]ork, uninterrupted,' '[l]ife, uninterrupted,' '[g]ame, uninterrupted,' '[c]hronic pain relief that supports functionality,' '[h]elps patients think less about their pain,' and '[i]mprove[s] . . . physical and social functioning.'" The September 2, 2004 letter states: "Janssen has not provided references to support these outcome claims. We are not aware of substantial evidence or substantial clinical experience to support these claims."¹⁷⁷

287. On July 15, 2005, the FDA issued a public health advisory warning doctors of deaths resulting from the use of Duragesic and its generic competitor, manufactured by Mylan N.V. The advisory noted that the FDA had been "'examining the circumstances of product use to determine if the reported adverse events may be related to inappropriate use of the patch'" and

¹⁷⁵ Warning Letter from Thomas W. Abrams, U.S. Department of Health and Human Services, to Ajit Shetty, Janssen Pharmaceutica, Inc., at 2 (Sept. 2, 2004).

¹⁷⁶ *Id.* at 2-3.

¹⁷⁷ *Id.* at 3.

noted the possibility “that patients and physicians might be unaware of the risks” of using the fentanyl transdermal patch, which is a potent opioid analgesic meant to treat chronic pain that does not respond to other painkillers.

288. Regardless, even after receiving these letters, Janssen instructed its sales representatives to market Duragesic as having better efficacy, better tolerability and better patient compliance because it was a patch instead of a pill. Janssen’s sales representatives were instructed to tell doctors that the patch provided better control in the event of patient opioid abuse because patients could not increase the patch dosage. However, sales representatives were aware of patients who increased the dosage by applying more than one patch at a time and were also aware that some patients abused the patch by freezing, then chewing on it.

ii. Janssen funded false publications and presentations

289. Despite repeated warnings, Janssen continued to falsely market the risks of opioids. In 2009, PriCara, a “Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.,” sponsored a 2009 brochure, “Finding Relief: Pain Management for Older Adults,” aimed at potential patients. The brochure represented that it was a source for older adults to gain accurate information about treatment options for effective pain relief:

This program is aimed specifically at older adults and what they need to know to get effective pain relief. You will learn that there are many pathways to this relief.

You will learn about your options for pain management and how to find the treatment that’s right for you. By learning more about pain and the many ways it can be treated, you are taking solid steps toward reducing the pain you or a loved one may be feeling.¹⁷⁸

290. Despite representing itself as a source of accurate information, the brochure

¹⁷⁸ *Finding Relief, Pain Management for Older Adults* (2009).

included false and misleading information about opioids, including a section seeking to dispel purported “myths” about opioid usage:

Opioid Myths

Myth: Opioid medications are always addictive.

Fact: Many studies show that opioids are *rarely* addictive when used properly for the management of chronic pain.

Myth: Opioids make it harder to function normally.

Fact: When used correctly for appropriate conditions, opioids may make it *easier* for people to live normally.

Myth: Opioid doses have to get bigger over time because the body gets used to them.

Fact: Unless the underlying cause of your pain gets worse (such as with cancer or arthritis), you will probably remain on the same dose or need only small increases over time.¹⁷⁹

291. Among the “Partners” listed in “Finding Relief: Pain Management for Older Adults” are the AAPM, the American Geriatrics Society (“AGS”) and the AGS Foundation for Health in Aging. Janssen (along with Purdue) funded AAPM. The AGS and the AGS Foundation for Health in Aging published a pain guide titled “Finding Relief: Pain Management for Older Adults,” which was funded by Janssen.

292. In addition, Janssen disseminated false information about opioids on the website Prescribe Responsibly, which remains publicly accessible at www.prescriberesponsibly.com. According to the website’s legal notice, all content on the site “is owned or controlled by

¹⁷⁹ *Id.*(emphasis in original).

Janssen.”¹⁸⁰ The website includes numerous false or misleading representations concerning the relative safety of opioids and omissions of the risks associated with taking them. For example, it states that while practitioners are often concerned about prescribing opioids due to “questions of addiction,” such concerns “are often overestimated. According to clinical opinion polls, true addiction occurs only in a small percentage of patients with chronic pain who receive chronic opioid analgesic[] . . . therapy.”¹⁸¹

293. Prescribe Responsibly also compared the risks of opioid use favorably to those associated with nonsteroidal anti-inflammatory drugs (“NSAIDs”), such as aspirin and ibuprofen, and stated that many patients develop tolerance for opioid side effects:

Opioid analgesics are often the first line of treatment for many painful conditions and may offer advantages over nonsteroidal anti-inflammatory drugs (NSAIDs). Opioid analgesics, for example, have no true ‘ceiling dose’ for analgesia and do not cause direct organ damage; however, they do have several possible side effects, including constipation, nausea, vomiting, a decrease in sexual interest, drowsiness, and respiratory depression. With the exception of constipation, many patients often develop tolerance to most of the opioid analgesic-related side effects.¹⁸²

294. Further, Prescribe Responsibly repeats the scientifically unsupported discussion of “pseudoaddiction” as “a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically when the pain is treated appropriately, the inappropriate behavior ceases.”¹⁸³ Thus, pseudoaddiction is defined as a condition requiring

¹⁸⁰ *Legal Notice*, Prescribe Responsibly. Available at: <https://www.prescriberesponsibly.com/legal-notice> (last visited Jan. 2, 2018).

¹⁸¹ *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly. Available at: <http://www.prescriberesponsibly.com/articles/opioid-pain-management> (last visited Jan. 2, 2018)

¹⁸² *Id.*

¹⁸³ *What a Prescriber Should Know Before Writing the First Prescription*, Prescribe Responsibly. Available at: <http://www.prescriberesponsibly.com/articles/before-prescribing-opioids> (last visited Jan. 2, 2018).

the prescription of more or stronger opioids.

295. As people became more and more hooked on prescription pain killers, they moved to heroin, and increasingly to fentanyl, which is even more potent and cheaper than heroin, and which as set forth above was being deceptively marketed by Janssen, causing a dramatic spike in heroin and fentanyl overdose deaths.

iii. Janssen failed to prevent diversion and to monitor, report, and stop suspicious orders of its prescription opioid products as required

296. The federal CSA imposes on all “registrants” the obligation to design and operate a system to disclose to the registrant suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. “Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”¹⁸⁴

297. Janssen is a “registrant” under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

298. Janssen failed to design and operate a system to disclose suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders.

299. By failing to prevent diversion and monitor, report, and stop suspicious orders of its prescription opioid products, Janssen knowingly entered and participated in the marketing of illegal drugs in New York. Janssen is aware of the extraordinary volume of opioid prescriptions in New York in relation to other states. Janssen knew that such inflated prescribing necessarily

¹⁸⁴ 21 C.F.R. §1301.74(b).

reflects improper prescribing and diversion of opioids, including Janssen's products.

300. Janssen further knowingly participated in the illegal drug market in New York and elsewhere by knowingly shirking its responsibility to detect and investigate suspicious orders, for which it was cited by the DEA, by deliberately and knowingly downplaying addiction risks associated with opioids and through the other knowing, fraudulent actions detailed in this Complaint. Those actions were designed to expand Janssen's market for opioids by inducing the medical community to overprescribe those drugs.

301. On information and belief, Janssen also knowingly participated in the illegal drug market in the in New York by supplying suspicious quantities of its products to suspect physicians and pharmacies in New York, without disclosing suspicious orders as required by applicable regulations.

V. The Distributor Defendants' Unlawful Conduct

A. The Distributor Defendants have a duty to report and stop suspicious orders of prescription opioids

302. Distributor Defendants have an affirmative duty to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs.

303. Congress created a closed system of distribution of prescription opioids with the Controlled Substance Act of 1970 ("CSA") that required all manufacturers and distributors to obtain registrations and investigate, report, and stop suspicious orders of prescription opioids.

304. The closed loop system established by the CSA combats diversion by requiring that "all legitimate handlers of controlled substances must obtain a DEA registration and, as a condition of maintaining such registration, must take reasonable steps to ensure that their registration is not

being utilized as a source of diversion.”¹⁸⁵

305. The CSA and its implementing regulations restrict the distribution of controlled substances by requiring drug distributors and manufacturers to monitor, identify, stop, and report suspicious orders of controlled substances, including orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.¹⁸⁶

306. The Distributor Defendants are required to register with the DEA, pursuant to the CSA.¹⁸⁷ Accordingly, each of the Defendant Distributors is a “registrant” as a wholesale distributor in the chain of distribution of Schedule II controlled substances (opioids) with a duty to comply with all security requirements imposed under that statutory scheme.

307. In evaluating a distributor’s operations, the DEA considers “(1) whether the distributor has maintained “effective control[s] against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels”; (2) whether the distributor has complied with applicable state and local laws; (3) whether the distributor has previously been convicted under federal or state laws for a crime related to the sale of controlled substances; (4) the distributor's past experience with controlled substances; and (5) “such other factors as may be relevant to and consistent with the public health and safety.”¹⁸⁸

308. Distributors are “one of the key components of the distribution chain” and “must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as Congress has expressly

¹⁸⁵ Letter from Joseph T. Rannazzisi, Deputy Assis. Admin., Office of Diversion Control, to Cardinal Health, Sept. 27, 2006, at 1 (filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW, Doc. 14-51 (D.D.C.)). (hereinafter “2006 Rannazzisi Letter”)

¹⁸⁶ See 21 U.S.C. §§ 801-971; 21 C.F.R. §§ 1300-1321.

¹⁸⁷ See 21 U.S.C. § 823(b), (e); 28 C.F.R. § 0.100; *Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 212 (D.C. Cir. 2017).

¹⁸⁸ *Masters Pharm., Inc.*, 861 F.3d at 212 (quoting 21 U.S.C. § 823(b), (e)).

declared that the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.”¹⁸⁹

309. Federal regulations require that Distributor Defendants “shall provide effective controls and procedures to guard against theft and diversion of controlled substances.”¹⁹⁰

310. Distributor Defendants must not ship a suspicious order.¹⁹¹ Every registrant under the CSA, including the Distributor Defendants, is required to notify the DEA of suspicious orders and stop such orders, thereby ensuring that prescription opioids are not diverted for illegal purposes.

311. The implementing federal regulations provide, “[t]he registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant.”¹⁹²

312. The regulations further provide that “[s]uspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”¹⁹³

The criteria for suspicious orders:

are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported a suspicious. Likewise, a registrant need not wait for a “normal pattern” to develop over time before determining whether a particular order is suspicious. The size of the order alone, whether or not it deviates

¹⁸⁹ 2006 Rannazzisi letter at 1.

¹⁹⁰ 21 C.F.R. § 1301.71(a). *See also* 21 U.S.C. § 823(b).

¹⁹¹ *See* Prevoznik, Thomas W., “Distributor Initiative: A National Perspective,” *Dea diversion.usdoj.gov*, U.S. Dept. of Justice, Drug Enforcement Administration, 22 Oct. 2013. Web. 25 Oct. 2017.

¹⁹² 21 C.F.R. § 1301.74(b).

¹⁹³ *Id.*

from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the relevant segment of the regulated industry.¹⁹⁴

313. "Once a distributor has reported a suspicious order, it must make one of two choices: decline to ship the order, or conduct some 'due diligence' and – if it is able to determine that the order is not likely to be diverted into illegal channels – ship the order."¹⁹⁵

314. New York also places duties on drug distributors as outlined in the New York Controlled Substances Act ("NYCSA"), N.Y. PHL §§3300 *et seq.* In terms of affirmative obligations, the NYCSA requires and pharmaceutical distributor selling controlled substances in New York to:

- (a) At the time of obtaining its initial license:
 - (i) Provide evidence that it is "able to maintain effective control against possible diversion...of controlled substances";¹⁹⁶
 - (ii) Provide evidence that it is "able to comply with all applicable state and federal laws";¹⁹⁷
 - (iii) State under penalty of perjury, whether or not I, or any of its employees, subsidiaries, managing officers, or directors "failed to comply with the...laws of any State relating to controlled substance," and if so, to submit a statement and explanatory documentation;¹⁹⁸

¹⁹⁴ Letter from Joseph T. Rannazzisi, Deputy Assis. Admin., Office of Diversion Control, to Cardinal Health, Dec. 27, 2007, at 1 (filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW, Doc. 14-8 (D.D.C.)). (hereinafter "2007 Rannazzisi Letter")

¹⁹⁵ *Masters Pharm., Inc.*, 861 F.3d at 212–13.

¹⁹⁶ N.Y. PHL § 3312(1)(c).

¹⁹⁷ N.Y. PHL § 3312(1)(d).

¹⁹⁸ *License Application to Engage in a Controlled Substance Activity*, N.Y. Department of Health Form 4330.

- (b) At the time of renewing its license:
 - (i) Report “any material change in the circumstances or factors” relevant to its initial license application;¹⁹⁹
 - (ii) Report all known governmental investigations of incidents involving the theft, loss, or possible diversion of controlled substances it distributed, or into its compliance with state or federal controlled substance laws;²⁰⁰
- (c) At all times:
 - (i) “[R]eport...any change in facts or circumstances...or any newly discovered or occurring fact or circumstance which is required to be included” in its application for an initial and/or renewal license;²⁰¹
 - (ii) “[N]otify the [state] of any incident involving the theft, loss or possible diversion of controlled substances...distributed by the licensee”;²⁰²
 - (iii) “[E]stablish and operate a system to disclose to the license[e] suspicious orders for controlled substances and inform the [New York State Department of Health] of such suspicious orders. Suspicious orders shall include, but not be limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”²⁰³

315. These affirmative obligations are complemented by one critical prohibition, contained within the very first operative subsection of the NYCSA: “It shall be unlawful for any person to...manufacture, sell, distribute...or transport a controlled substance except as expressly allowed by this article.”²⁰⁴

316. In order to deter and remedy violations of these duties, and ensure that

¹⁹⁹ N.Y. PHL § 3312(2)(a).

²⁰⁰ N.Y. PHL § 3312(2)(b).

²⁰¹ N.Y. PHL § 3312(3), 3315(3)

²⁰² N.Y. PHL § 3322(3).

²⁰³ 10 NYCRR § 80.22.

²⁰⁴ N.Y. PHL § 3304(1)

manufacturers and distributors fulfill their critical role in preventing the improper use of controlled substances, New York law requires that any distributor who “violates, disobeys, or disregards” any provision of the NYCSA be assessed a separate and substantial civil penalty *“for every such violation.”*²⁰⁵

317. That penalty is set at a minimum amount of \$2,000 per violation,²⁰⁶ but can be increased to \$5,000 for any subsequent violation within twelve months of the first where both violations “were a serious threat to the health and safety of an individual or individuals,”²⁰⁷ and to \$10,000 for each violation that “directly results in serious physical harm to any patient or patients.”²⁰⁸

318. Companies subject to the NYCSA are expected to develop and enforce specific written policies to ensure compliance which are sometimes referred to as controlled substance monitoring programs (“CSMPs”) or order monitoring programs (“OMPs”). These policies are supposed to explain for compliance staff how the company determines what a suspicious order is and how suspicious order reports (“SORs”) to the State and other regulators are to be made.

319. The NYCSA, as noted above, includes a non-exclusive list of factors to be considered in monitoring potentially-suspicious orders. But companies subject to the NYCSA, including all of the Distributor Defendants here, typically have (or should have) a wealth of additional data to rely on, including their customers’ relative reliance on cash payments, prior business with suspect prescribers, and the number and frequency of times that their customers have exceeded periodic limits (usually 30-day limits called “thresholds”) for ordering controlled

²⁰⁵ N.Y. PHL § 3396(2) (emphasis added).

²⁰⁶ N.Y. PHL § 12(1)(a).

²⁰⁷ N.Y. PHL § 12(1)(b).

²⁰⁸ N.Y. PHL § 12(1)(c).

substances, or made requests for increases in those thresholds (“threshold change requests”).

320. The Distributor Defendants knew they were required to monitor, detect, and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, explain that distributors are “[a]t the center of a sophisticated supply chain” and therefore “are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers.”²⁰⁹ The guidelines set forth the recommended steps in the “due diligence” process, and note in particular “[i]f an order meets or exceeds a distributor’s threshold, as defined in the distributor’s monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.”²¹⁰

321. The Distributor Defendants sold prescription opioids in and around Rockland County, which Defendants knew were likely to be diverted in Rockland County.

322. Each Distributor Defendant owes a duty to monitor and detect suspicious orders of prescription opioids.

323. Each Distributor Defendant owes a duty to investigate and refuse suspicious orders of prescription opioids.

324. Each Distributor Defendant owes a duty to report suspicious orders of prescription opioids.

²⁰⁹ Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances (filed in *Cardinal Health, Inc. v. Holder*, No. 12-5061, Doc. No. 1362415 (App’x B) (D.C. Cir. Mar. 7, 2012)).

²¹⁰ *Id.*

325. Each Distributor Defendant owes a duty to prevent the diversion of prescription opioids into illicit markets in New York and Rockland County.

B. The Distributor Defendants breached their duties and the DEA gets involved

i. The Distributor Defendants failed to report and stop suspicious opioid orders

326. “Because distributors handle such large volumes of controlled substances and are the first major line of defense in the movement of legal pharmaceutical controlled substances . . . from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system created by the CSA collapses.”²¹¹

327. The sheer volume of prescription opioids distributed to pharmacies in Rockland County and/or to pharmacies from which the Distributor Defendants knew the opioids were likely to be diverted into Rockland County, is excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.

328. The Distributor Defendants failed to report suspicious orders originating from Rockland County or which the Distributor Defendants knew were likely to be diverted to Rockland County, to the federal and state authorities, including the DEA and the New York Board of Pharmacy.

329. The Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern and/or orders of unusual frequency in Rockland County, and/or orders which Defendants knew or should have known were likely to be

²¹¹ Declaration of Joseph Rannazzisi, ¶ 10 (filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW, Doc. 14-2 (D.D.C. February 10, 2012)).

delivered and/or diverted into Rockland County.

330. The Distributor Defendants breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opioids originating from Rockland County, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted to Rockland County.

331. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opioids into other than legitimate medical, scientific, and industrial channels.

332. The Distributor Defendants breached their duty to design and operate a system to disclose suspicious orders of controlled substances and failed to inform state and federal authorities of suspicious orders when discovered, in violation of their duties under federal and state law.

333. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.

334. The unlawful conduct by the Distributor Defendants is purposeful and intentional. The Distributor Defendants violated the duties imposed by federal and state law.

335. The Distributor Defendants acted with actual malice in breaching their duties, i.e., they have acted with a conscious disregard for the rights and safety of other persons, and their actions had and continue to have a great probability of causing substantial harm.

336. The Distributor Defendants' repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive

damages.

337. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes and the subsequent opioid addiction crisis ravaging New York and Rockland County and the damages caused thereby.

ii. The DEA sent warning letters to the Distributor Defendants

338. As a result of the Distributor Defendants' failure to comply with federal law, the DEA has taken a number of actions against them.

339. On September 27, 2006, the DEA sent a letter to "every commercial entity in the United States registered with the [DEA] to distribute controlled substances."²¹²

340. The letter stated that manufacturers and distributors "share responsibility for maintaining appropriate safeguards against diversion" and "given the extent of prescription drug abuse in the United States, along with the dangerous and potentially lethal consequences of such abuse, **even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.**"²¹³

341. The letter advised that the "DEA will use its authority to revoke and suspend registrations in appropriate cases."²¹⁴

342. The letter also provides that "in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."²¹⁵

343. The letter further discusses that "distributors must be vigilant in deciding whether

²¹² 2006 Rannazzisi Letter at 1.

²¹³ *Id.* at 2 (emphasis added).

²¹⁴ *Id.*

²¹⁵ *Id.*

a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as Congress has expressly declared that the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.”²¹⁶

344. The DEA sent another letter on December 27, 2007 to “reiterate the responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders.”²¹⁷

345. This letter reminded manufacturers and distributors of their obligation to “maintain effective controls against diversion” and “design and operate a system to disclose to the registrant suspicious orders of controlled substances.”²¹⁸

346. The letter stated that in terms of reporting suspicious orders:

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communications with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by a registrant indicating “excessive purchases” do not comply with the requirement to report suspicious orders, even

²¹⁶ *Id.* at 1.

²¹⁷ 2007 Rannazzisi Letter at 1.

²¹⁸ *Id.*

if the registrant calls such reports “suspicious order reports.”²¹⁹

347. The 2007 letter also said that “[f]ailure to maintain effective controls against diversion is inconsistent with the public interest . . . and may result in the revocation of the registrant’s DEA Certificate of Registration.”²²⁰

348. The 2007 letter also references the final order issued in *Southwood Pharmaceuticals, Inc.*, 72 FR 36487 (2007), which “[i]n addition to discussing the obligation to report suspicious orders when discovered” and “some criteria to use when determining whether an order is suspicious,” the order “also specifically discusses your obligation to maintain effective controls against the diversion of controlled substances.”²²¹

349. The 2007 letter also references the DEA’s final order issued in *Southwood Pharmaceuticals, Inc.*, 72 FR 36487-01 (2007), which “[i]n addition to discussing the obligation to report suspicious orders when discovered” and “some criteria to use when determining whether an order is suspicious,” the order “also specifically discusses [Southwood’s] obligation to maintain effective controls against the diversion of controlled substances.”²²²

iii. DEA actions against the Distributor Defendants

350. Under the CSA, the DEA may revoke or suspend an entity’s registration for committing “such acts as would render his registration [under the CSA] inconsistent with the public interest.”²²³ Typically, before suspending or revoking a registration, the DEA must issue an order to show cause, outlining its basis for the proceedings. However, in instances where the DEA has reason to believe that a registrant’s continued operation would pose “an imminent danger

²¹⁹ *Id.* at 2.

²²⁰ *Id.* at 1-2.

²²¹ *Id.* at 2.

²²² *Id.* at 2.

²²³ 21 U.S.C. § 824.

to the public health or safety,” the DEA may suspend the entity’s registration immediately by issuing an Immediate Suspension Order (“ISO”) pursuant to Section 824(d) of the CSA.

351. Because of the Distributor Defendants’ refusal to comply with their legal obligations, the DEA has repeatedly taken administrative action to force compliance. The United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Division, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012.²²⁴ “The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.”²²⁵

352. **AmerisourceBergen**: On April 24, 2007, the DEA issued an ISO on AmerisourceBergen’s Orlando, Florida distribution center, alleging that AmerisourceBergen was not controlling shipments of prescription opioids to Internet pharmacies and revoking the facility’s license to distribute controlled substances.²²⁶

353. On June 22, 2007, AmerisourceBergen entered into a settlement with the DEA which lead to the reinstatement of the Orlando distribution center’s suspended license.²²⁷ Under that agreement, AmerisourceBergen was required to implement an enhanced order-monitoring program in all of its distribution centers by June 30, 2007.²²⁸

354. In 2012, West Virginia’s then-Attorney General Darrell McGraw filed lawsuits

²²⁴ “The Drug Enforcement Administration’s Adjudication of Registrant Actions,” *Oig.justice.gov*, United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, I-2014-003, p. 6 (May 2014).

²²⁵ *Id.*

²²⁶ 2007 AmerisourceBergen Corporation Form-10K. Available at: <https://www.sec.gov/Archives/edgar/data/1140859/000119312507255013/d10k.htm>.

²²⁷ *Id.*

²²⁸ *Id.*

against AmerisourceBergen, Cardinal Health, and a dozen smaller drug distributors for their role in a drug supply chain that includes doctors who write prescriptions for nonmedical purposes and “pill mill” pharmacies that dispense excessive numbers of painkillers, including opioids.²²⁹ In February 2017, Cardinal Health and AmerisourceBergen agreed to pay \$20 million and \$16 million, respectively, to resolve West Virginia’s claims.²³⁰

355. The settlement, which is believed to be the largest pharmaceutical settlement in West Virginia history, came shortly after a Charleston Gazette-Mail investigation revealed that drug wholesalers shipped 780 million hydrocodone and oxycodone pills to West Virginia in just six years – a period when 1,728 West Virginians fatally overdosed on those two drugs.²³¹ Cardinal Health and AmerisourceBergen combined to ship nearly 40 percent of all hydrocodone and oxycodone pills to West Virginia.²³²

356. According to unsealed court documents from the West Virginia case, AmerisourceBergen distributed 149,300 hydrocodone pills – or 12,400 pills a month – to Tug Valley Pharmacy in Mingo County in 2009.²³³ The pharmacy filled prescriptions for Drs. Diane Shafer, Katherine Hoover and William Rykman, who operated “sham” pain clinics in Williamson.²³⁴ Federal agents raided the clinics in 2010 and they never reopened.²³⁵

357. Unsealed court documents from that case further evidence that AmerisourceBergen

²²⁹ Eric Eyre, *2 drug distributors to pay \$36M to settle WV painkiller lawsuits*, Charleston Gazette-Mail, January 9, 2017. Available at: <http://www.wvgazettemail.com/news-cops-and-courts/20170109/2-drug-distributors-to-pay-36m-to-settle-wv-painkiller-lawsuits>.

²³⁰ *Id.*

²³¹ *Id.*

²³² *Id.*

²³³ Eric Eyre, *18 ‘words’ reveal drug giant’s pain pill shipments to WV*, Charleston Gazette-Mail, May 25, 2016. Available at: <http://www.wvgazettemail.com/news/20160525/18-words-reveal-drug-giants-pain-pill-shipments-to-wv>.

²³⁴ *Id.*

²³⁵ *Id.*

shipped 8,000 hydrocodone painkiller tablets to a drive-thru pharmacy over two days in July 2012.²³⁶ On those same two days, a competing drug wholesaler shipped 8,600 hydrocodone tablets to the same “pill mill” pharmacy.²³⁷ AmerisourceBergen sold another 3,800 oxycodone pills to the Boone County pharmacy that month.²³⁸

358. **Cardinal Health**: Based on findings from DEA investigations, in November and December 2007, the DEA issued three ISOs to Cardinal Health.

359. On November 28, 2007, the DEA issued an ISO to Cardinal Health in connection with its distribution center in Auburn, Washington (the “Auburn Facility”), immediately suspending the facility’s Certificate of Registration because its continued registration constituted “an imminent danger to public health and safety.”²³⁹

360. According to the ISO, the Auburn Facility repeatedly “distributed unusually large amounts of hydrocodone” to Horen’s Drugstore, Inc. (“Horen’s Drugstore”) – distributing 600,000 dosage units of hydrocodone to Horen’s Drugstore from March 2007 through September 2007 – and “disregard[ed] the clear indications that Horen’s Drugstore was engaged in the diversion of controlled substances[.]” Horen’s Drugstore was Cardinal Health’s largest purchaser of combination hydrocodone products in 2007, and according to the ISO, the drugstore was “a pharmacy engaged in a scheme to dispense controlled substances based on prescriptions that are issued for other than a legitimate medical purpose and by physicians acting outside the usual course of professional practice. This pharmacy dispensed excessive amounts of hydrocodone based on

²³⁶ *Id.*

²³⁷ *Id.*

²³⁸ *Id.*

²³⁹ *Cardinal Health, Inc. v. Holder*, Case No. 1:12-cv-00185, Dkt. 14-15 (“Settlement and Release Agreement and Administrative Memorandum of Agreement”), ¶ 2, Appendix B (D.D.C. 2012). (Hereinafter “2008 Cardinal Health MOA”)

illegitimate prescriptions originating from rogue Internet pharmacy websites, in violation of applicable Federal and State law.” The DEA found that Cardinal Health “failed to maintain effective controls against diversion of a particular controlled substance into other than legitimate medical, scientific and industrial channels,” and concluded that its continued registration with the DEA constituted “an imminent danger to the public health and safety.”

361. On December 5, 2007, the DEA issued an ISO notifying Cardinal Health of the immediate suspension of its Lakeland, Florida drug distribution facility.²⁴⁰

362. The ISO detailed how, from August 2005 through October 2007, Cardinal Health failed to maintain effective controls against the diversion of hydrocodone into other than legitimate medical, scientific and industrial channels. According to the ISO, Cardinal Health distributed hydrocodone to various pharmacies, even though the company knew that many of the orders placed by the pharmacies were of an unusual size and were “suspicious” as defined in the CSA. For example, Cardinal Health distributed 1,213,000 dosage units of hydrocodone to Q-R-G, Inc. over the course of February to June 2006, and approximately 1,148,100 dosage units to United Prescription Services, Inc. from July to October 2006. The ISO further detailed that, on September 1, 2006, Eric Brantley, Manager of Quality and Regulatory Affairs for Cardinal Health, sent an email to the DEA stating that Cardinal Health discontinued all sales of controlled substances to 13 Internet pharmacies, including RKR Holdings, Inc. Nevertheless, from September 1, 2006 to January 31, 2007, Cardinal Health distributed 393,600 dosage units of hydrocodone products to RKR Holdings.

363. On December 7, 2007, the DEA issued an ISO to Cardinal Health regarding its distribution center in Swedesboro, New Jersey which, from January 2005 to August 2007,

²⁴⁰ 2008 Cardinal Health MOA, ¶ 3, Appendix C.

“distributed over 4.5 million dosage units of combination hydrocodone products to customers that it knew or should have known were diverting hydrocodone into other than legitimate medical, scientific and industrial channels.”²⁴¹

364. The ISO stated that some of Cardinal Health’s “largest purchasers of combination hydrocodone products were pharmacies engaged in a scheme to distribute controlled substances based on purported prescriptions that were issued for other than a legitimate medical purpose and by physicians acting outside the usual course of professional practice.”

365. In addition to the November and December 2007 ISOs, the DEA issued an Order to Show Cause as to why the agency should not revoke the Certificate of Registration assigned to the company’s Stafford, Texas distribution center for the improper distribution of hydrocodone.²⁴² The DEA also found that Cardinal failed to maintain effective controls against the diversion of controlled substances at its McDonough, Georgia facility, Valencia, California facility, and Denver, Colorado facility.²⁴³ ***In total, the DEA had reason to believe that seven of Cardinal’s twenty-seven then-registered distribution centers were not adhering to their obligations under the CSA.***

366. Following the three 2007 ISOs and the Order to Show Cause, the DEA and Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement (“MOA”) on September 29, 2008.²⁴⁴ Pursuant to the MOA, Cardinal Health agreed to pay a civil fine of \$34 million, and “maintain a compliance program designed to protect and prevent diversion of controlled substances as required under the CSA and applicable DEA

²⁴¹ *Id.* at ¶ 4, Appendix D.

²⁴² *Id.* at ¶ 5, Appendix E.

²⁴³ *Id.* at ¶ 7.

²⁴⁴ *Id.*

regulations.”²⁴⁵

367. After entry of the 2008 MOA, Cardinal Health began violating the CSA again almost immediately. A further investigation of Cardinal Health’s Lakeland, Florida facility by the DEA “revealed a persistent failure to exercise due diligence to ensure that controlled substances were not being diverted” over a period of approximately three years, from November 2008 to December 2011.²⁴⁶ The lack of anti-diversion controls resulted in the top four customers of Cardinal Health’s Lakeland facility being supplied with approximately 50 times the amount of oxycodone compared to the average Florida retailer that Cardinal Health services, which the DEA referred to as a “staggering” difference in distribution.²⁴⁷

368. The DEA’s further investigation culminated in the issuance of another ISO regarding the Lakeland facility on February 2, 2012 (the “2012 ISO”).²⁴⁸

369. The 2012 ISO stated that, “[d]espite the MOA, the specific guidance to Cardinal by DEA, and despite the public information readily available regarding the oxycodone epidemic in Florida, Cardinal has failed to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific, and industrial channels, in violation of [the CSA].”²⁴⁹ According to the ISO:

From January 1, 2008 through December 31, 2011 . . . Cardinal’s sales of oxycodone products to its top four retail pharmacy customers exceeded 12.9 million dosage units. . . . From 2008 to 2009, Cardinal’s sales to its top four retail pharmacy customers increased approximately 803%. From 2009 to 2010, Cardinal’s

²⁴⁵ *Id.*

²⁴⁶ *Cardinal Health, Inc. v. Holder*, Case No. 1:12-cv-00185, Dkt. 14-2 (“Declaration of Joseph Rannazzisi, Deputy Assistant Administrator for the DEA’s Office of Diversion Control”), ¶ 75 (D.D.C. 2012).

²⁴⁷ *Id.* at ¶ 76.

²⁴⁸ *Cardinal Health, Inc. v. Holder*, Case No. 1:12-cv-00185, Dkt. 14-18 (D.D.C. 2012).

²⁴⁹ *Id.* at ¶ 3.

sales to its top four retail pharmacy customers increased approximately 162%. [¶] The egregious quantities of oxycodone distributed by Cardinal to its top four retail pharmacy customers well exceeded the amount of oxycodone distributed to Cardinal's Florida retail pharmacies, which receive, on average, approximately 5,347 dosage units of oxycodone per month.²⁵⁰

370. The 2012 ISO further provided that “[n]otwithstanding the large quantities of controlled substances ordered by Cardinal’s top retail pharmacy customers, Cardinal failed to conduct meaningful due diligence to ensure that the controlled substances were not diverted into other than legitimate channels, including Cardinal’s failure to conduct due diligence of its retail pharmacy chain customers.”²⁵¹

371. On December 23, 2016, Cardinal Health agreed to pay a \$34 million fine (separate from the \$34 million fine in 2008) to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center.²⁵²

372. **McKesson**: On May 2, 2008, McKesson agreed to pay a total of \$13.25 million in civil penalties to six U.S. Attorney’s Offices to settle allegations that the company violated federal reporting provisions relating to its handling of prescription painkillers, including hydrocodone.²⁵³

373. In a press release regarding the agreement, the Department of Justice explained:

Three McKesson distribution centers received and filled hundreds of suspicious orders placed by pharmacies participating in illicit Internet schemes, but failed to report the orders to DEA. They did so even after a Sept.1, 2005, meeting at which DEA officials met

²⁵⁰ *Id.* at ¶ 4.

²⁵¹ *Id.* at ¶ 5.

²⁵² Press Release, *United States Reaches \$34 Million Settlement With Cardinal Health For Civil Penalties Under The Controlled Substances Act*, DOJ, U.S. Attorney’s Office – Middle District of Florida. Available at: <https://www.justice.gov/usao-mdfl/pr/united-states-reaches-34-million-settlement-cardinal-health-civil-penalties-under>.

²⁵³ Press Release, *McKesson Corporation Agrees to Pay More than \$13 Million to Settle Claims that it Failed to Report Suspicious Sales of Prescription Medications*, Dept. of Justice, May 2, 2008. Available at: <https://www.justice.gov/archive/opa/pr/2008/May/08-opa-374.html>.

with and warned McKesson officials about excessive sales of their products to pharmacies filling illegal online prescriptions. The pharmacies filled purported online “prescriptions” for hydrocodone (contained in drugs such as Vicodin), but the prescriptions were issued outside the normal course of professional practice and not for a legitimate medical purpose. The United States Attorneys allege that the orders that McKesson received from these pharmacies were unusually large, unusually frequent, and/or deviated substantially from the normal pattern. As a result, millions of dosage units of controlled substances were diverted from legitimate channels of distribution.²⁵⁴

374. As part of the 2008 agreement, McKesson was required to “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders . . . and follow procedures established by [McKesson’s] Controlled Substance Monitoring Program (“CSMP”).”²⁵⁵ McKesson flagrantly violated those provisions of the agreement.

375. A federal government investigation revealed that, from 2008 to 2013, McKesson did not fully implement its compliance program, and, instead, supplied various U.S. pharmacies an increasing amount of oxycodone and hydrocodone pills.²⁵⁶ For example, in Colorado, McKesson processed more than 1.6 million orders for controlled substances from June 2008 through May 2013, but reported just 16 orders as suspicious.²⁵⁷

376. When confronted with the evidence gathered in the government’s investigation,

²⁵⁴ *Id.*

²⁵⁵ 2017 Administrative Memorandum of Agreement (DOJ, DEA and McKesson). Available at: <https://www.justice.gov/opa/press-release/file/928476/download>. (Hereinafter “2017 McKesson MOA”).

²⁵⁶ Press Release, *McKesson Agrees to Pay Record \$150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs*, Dept. of Justice, January 17, 2017. Available at: <https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders>.

²⁵⁷ *Id.*

McKesson conceded that, following the 2008 agreement, the company:

- “[F]ailed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA . . . at the McKesson Distribution Centers” located in: Aurora, Colorado; Aurora, Illinois; Delran, New Jersey; LaCrosse, Wisconsin; Lakeland, Florida; Landover, Maryland; La Vista, Nebraska; Livonia, Michigan; Methuen, Massachusetts; Santa Fe Springs California; Washington Courthouse, Ohio; and West Sacramento, California;²⁵⁸
- “[F]ailed to properly monitor its sales of all controlled substances and report suspicious orders to DEA, in accordance with McKesson’s obligations under the 2008 Agreements”;²⁵⁹
- “[F]ailed to conduct due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers, and bypassed suspicious reporting procedures set forth in the McKesson CSMP”;²⁶⁰
- “[F]ailed to inform the DEA Field Division Offices and/or DEA Headquarters of certain suspicious orders of controlled substances made by its customers during the relevant time period, including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency”;²⁶¹
- “[F]ailed to report suspicious orders for certain controlled substances in accordance with the standards identified and outlined in the DEA Letters”;²⁶² and
- “[D]istributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners in

²⁵⁸ 2017 McKesson MOA at 3.

²⁵⁹ *Id.* at 4.

²⁶⁰ *Id.*

²⁶¹ *Id.*

²⁶² *Id.*

the usual course of their professional practice.”²⁶³

377. Following the federal government’s investigation, in January 2017, McKesson entered into an Administrative Memorandum of Agreement with the DEA wherein it agreed to pay a \$150,000,000 civil penalty for violation of the 2008 agreement as well as failure to identify and report suspicious orders of controlled substances at its drug distribution centers across the country.²⁶⁴ The 2017 agreement further required McKesson to suspend sales of controlled substances from its distribution centers in Colorado, Ohio, Michigan and Florida for multiple years.²⁶⁵ The suspensions are among the most severe sanctions ever agreed to by a DEA registered distributor.

378. **Rochester Drug:** Since its founding in 1905, Rochester Drug has grown to be the sixth largest pharmaceutical distributor in the country. Rochester has a large distribution center in New Jersey, which supplies many New York City, and on information and belief, Rockland County, Retailers with opioid products.

379. In 2015, Rochester Drug settled a civil lawsuit brought by the Federal government, paying \$360,000 in penalties after admitting that it did not report thousands of potentially suspicious orders to the DEA, as required by federal and New York law.

380. In 2019, Rochester Drug was the first in the nation to be charged by the federal government with criminal charges against the company and two executives for the diversion of opioids to illicit markets.

381. Shortly thereafter, Rochester Drug entered into its second civil settlement with the federal government in less than five years, paying \$20 million and agreeing to even more stringent

²⁶³ *Id.*

²⁶⁴ 2017 McKesson MOA at 8.

²⁶⁵ *Id.* at 5 – 7.

monitoring and reporting requirements.

382. Rochester Drugs knew that it had a responsibility to prevent diversion through adherence to federal and state laws and regulations designed to prevent the diversion of controlled substances, but it chose instead, to place profits over people and participate in the diversion of opioids into unsuspecting counties, like Rockland County.

iv. The Distributor Defendants misled the public concerning their duties and compliance

383. In *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration* (D.C. Cir), the Healthcare Distribution Management Association (“HDMA”), a trade association run by the Distributor Defendants, and National Association of Chain Drug Stores (“NACDS”) submitted briefs regarding the legal duty of wholesale distributors.²⁶⁶ Inaccurately denying the legal duties that Distributor Defendants have failed to fulfill, they argued that:

- The Associations complained that the “DEA has required distributors not only to report suspicious orders, but to *investigate* orders (e.g., by interrogating pharmacies and physicians) and take action to *halt* suspicious orders before they are filled.”²⁶⁷
- The Associations argued that, “DEA now appears to have changed its position to require that distributors not only *report* suspicious orders, but *investigate* and *halt* suspicious orders. 80 Fed. Reg. at 55,421, 55,475-77, 55,479. Such a change in agency position must be accompanied by an

²⁶⁶ The HDMA – now known as the Healthcare Distribution Alliance (“HAD”) – is a national, not-for-profit trade association that represents the nation’s primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen, Cardinal Health, and McKesson. *See generally* HDA, About, <https://www.healthcaredistribution.org/about>. The NACDS is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart. *See generally* NACDS, Mission, <https://www.nacds.org/about/mission/>.

²⁶⁷ Brief for HDMA and NACDS filed in *Masters Pharm., Inc. v. Drug Enf’t Admin.*, USCA Case #15-1335, Doc. No. 1607110, at 4–5 (D.C. Cir. Apr. 4, 2016).

acknowledgement of the change and a reasoned explanation for it. In other words, an agency must “display awareness that it is changing position” and “show that there are good reasons for the new policy.” *Fox Television Stations, Inc.*, 556 U.S. at 515. This is especially important here, because imposing intrusive obligations on distributors threatens to disrupt patient access to needed prescription medications.”²⁶⁸

- The Associations alleged “Section 1301.71 by its terms restricts DEA’s authority to delineate the requirements for “effective controls” – stating that, in evaluating a control system, the Administrator “shall use the security requirements set forth in §§ 1301.72-1301.76.” 21 C.F.R. § 1301.71(a) (emphasis added). Nothing in Sections 1301.72-1301.76 requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious.”²⁶⁹
- The Associations complained that the purported “practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties.”²⁷⁰
- The Associations alleged (inaccurately) that “DEA’s regulations had sensibly imposed a duty on distributors simply to report suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders.”²⁷¹
- Also inaccurately, the Associations argued that, “[i]mposing a duty on distributors – which lack the patient information and the necessary medical expertise – to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA’s demands.”²⁷²

384. Rejecting the Associations’ contentions, the United States Court of Appeals for the District of Columbia issued an opinion stating that “[o]nce a distributor has reported a suspicious order, it must make one of two choices: decline to ship the order, or conduct some “due diligence” and – if it is able to determine that the order is not likely to be diverted into illegal channels – ship

²⁶⁸ *Id.* at 8.

²⁶⁹ *Id.* at 14.

²⁷⁰ *Id.* at 22.

²⁷¹ *Id.* at 24-25.

²⁷² *Id.* at 26.

the order (the Shipping Requirement).”²⁷³

385. The Distributor Defendants have also undertaken to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

386. For example, a Cardinal Health executive said the company “deploys ‘advanced analytics, technology, and teams of anti-diversion specialists and investigators who are embedded in our supply chain. This ensures that we are as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.’”²⁷⁴

387. Given the sales volumes and the company’s history of violations, this executive was either not telling the truth, or Cardinal Health had such a system, but it ignored the results.

388. Similarly, McKesson publicly stated that it has “put significant resources towards building a best-in-class controlled substance monitoring program to help identify suspicious orders and prevent prescription drug diversion in the supply chain,” and “[o]ur team is deeply passionate about curbing the opioid epidemic in our country.”²⁷⁵

389. Given McKesson’s past conduct, this statement is either false, or the company ignored the results of its monitoring program.

390. Rather than abide by their duties, the Distributor Defendants and their association, the Healthcare Distribution Alliance, spent \$13 million to lobby House and Senate members and their staff in favor of legislation called “Ensuring Patient Access and Effective Drug Enforcement

²⁷³ *Masters Pharm., Inc.*, 861 F.3d at 212–13.

²⁷⁴ Bernstein, Lenny et al., “How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: ‘No one was doing their job,’” *The Washington Post*, 22 Oct. 2016.

²⁷⁵ Higham, Scott et al., “Drug Industry Hired Dozens of Officials from the DEA as the Agency tried to Curb Opioid Abuse,” *The Washington Post*, 22 Dec. 2016.

Act” which, as one article described, “raises the standard for the diversion office to obtain an immediate suspension order. Now the DEA must show an “immediate” rather than an “imminent” threat to the public, a nearly impossible burden to meet against distributors, according to former DEA supervisors and other critics. They said the new law gives the industry something it has desperately sought: protection from having its drugs locked up with little notice.”²⁷⁶ After an explosive media report on the Distributor Defendants’ lobbying effort, the Congressman who sponsored the bill and who was slated to be the President’s new Drug Czar, withdrew his name from consideration.

391. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts giving rise to the claims that County of Rockland now asserts.

392. In September 2017, 41 state Attorneys General served opioid manufacturers and distributors with subpoenas and document requests seeking information concerning how the companies marketed and distributed opioids.²⁷⁷

393. Meanwhile, the opioid epidemic ravages Rockland County because the fines and suspensions imposed by the DEA did not change the conduct of Distributor Defendants. The Distributor Defendants simply pay fines as a cost of doing business in their industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility.

394. The Distributor Defendants have abandoned their duties imposed under federal and

²⁷⁶ Bernstein, Lenny et al, “Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control,” *The Washington Post*, 22 Oct. 2016.

²⁷⁷ Press Release, “A.G. Schneiderman, Bipartisan Coalition Of AGs Expand Multistate Investigation Into Opioid Crisis,” *New York State Office of the Attorney General*, 19 Sept. 2017.

state law, taken advantage of a lack of DEA law enforcement, and allowed diversion in New York and Rockland County for their economic benefit.

VI. The Retailer Defendants' Unlawful Conduct

A. The Retailer Defendants Also Engaged in Unlawful Conduct and Otherwise Facilitated Diversion

395. The Retailer Defendants knowingly filled prescriptions for obviously suspect prescribers and pill mills. Upon information and belief, the Retailer filled prescriptions for Prescriber Defendants in this action, the pill mill operators and other suspect prescribers specifically identified above, and pill operators and other suspect prescribers in New York and the Counties.

396. The Retailer Defendants also over-supplied New York and the Counties with opioids at levels far exceeding any conceivable medical need.

397. Pharmacies are the final step on the pharmaceutical supply chain before drugs reach a patient. Pharmacies purchase drugs from wholesalers, including the Distributor Defendants, and occasionally from manufactures directly (upon information and belief, including the Producer Defendants here). Pharmacies maintain accurate, detailed data concerning the prescribing habits of individual prescribers. Upon information and belief, the Retailer Defendants maintained this data relative to New York prescribers (including those in or serving the Counties) and provided that data to the Producer Defendants and/or Distributor Defendants in return for rebates or other forms of consideration.

398. Pharmacies are the last line of defense in keeping drugs out of the illegal market. Under New York law, pharmacies and pharmacists have heightened obligations to ensure that they only dispense prescriptions that they believe are for a medically necessary purpose.²⁷⁸ New York

²⁷⁸ See NY PHL § 3333

pharmacies must also maintain detailed data for everyone who fills prescriptions at the pharmacy, including where that person is from, their age, and their individual prescribing history.²⁷⁹ They must also record and maintain records of all prescriptions dispensed, including the type of medication, the amount, and the prescriber.²⁸⁰ Pharmacists are also limited to dispensing prescriptions only at a rate, based on the actual number of medical and prescriptions order compounded and dispensed per hour or per day, that does not pose a danger to the public health, safety or welfare.²⁸¹ Pharmacies also may not dispense medications unless they determine that it will not be subject to clinical abuse/misuse.²⁸²

399. Pharmacies, including the Retailer Defendants, also must register for New York's Controlled Substance Monitoring Database ("CSMD"), to which they must periodically submit specific information that includes, *inter alia*, the date of each prescription, the amount, the strength, the patient name, and the prescriber.²⁸³

400. The Retailer Defendants have no obligation to dispense a prescription that is suspicious or even questionable. To the contrary, they not supposed to fill any order absent a determination that the order is lawful and/or will not be abused. In other words, the Retailer Defendants are not automatons in the supply chain. Every prescription they fill reflects a conscious, affirmative act that New York regulates.

401. Upon information and belief, the Retailer Defendants (like the other defendants) implemented policies designed to incentivize filling suspicious orders and to minimize the likelihood that any pharmacy would refuse to fill certain orders or otherwise report any prescribers

²⁷⁹ NY PHL § 3343, -a.

²⁸⁰ *Id.*

²⁸¹ NY PHL § 3333(1)

²⁸² NY PHL §§ 3350 *et seq.*

²⁸³ NY PHL § 3343-a

to law enforcement.

402. The Retailer Defendants adopted policies, including performance metrics and quotes, that facilitated diversion of their drugs. For example, CVS adopted a policy called The Metrics System, which rates its retail stores' pharmacists and employees based solely on *productivity* – namely, how many and how quickly those stores filled prescription each day based on store volume. These requirements placed significant and unrealistic time pressures on pharmacists. This created a perverse incentive for their retail stores to fill orders (including suspicious orders and pill mill prescriptions) without regard to whether the orders themselves were legitimate. Upon information and belief, the Retailer Defendants required pharmacists to fill one prescription every three minutes. Upon information and belief, the targets set in these types of programs effectively required pharmacists to fill prescriptions in violation of their professional responsibilities, including filling prescriptions at volumes that plainly exceeded any conceivable medical need or legitimate purpose, filling prescriptions in large volumes from out-of-state or out-of-county residents, and filling prescriptions for individuals that the Retailer Defendants knew were drug addicts or pill seekers.

403. Upon information and belief, the Retailer Defendants also paid productivity-based bonuses to their pharmacists, providing additional incentives to fill suspicious prescriptions.

404. Upon information and belief, the Retailer Defendants required their employee pharmacists to fill more than 600 prescriptions per work shift in some circumstances.

405. By the same token, upon information and belief, the Retailer Defendants did not routinely measure their employees' performance relative to pharmacy accuracy, customer safety, or processing only non-suspicious orders for a legitimate medical purpose.

406. In these ways, the Retailer Defendants financially incentivized their pharmacists

to fill suspicious orders and/or to fill orders without adequate due diligence.

407. Upon information and belief, the Retailer Defendants did not adequately train their pharmacists and pharmacy technicians on how to identify prescription drug abuse and illegitimate orders.

408. In an addition to these financial incentives, the Retailer Defendants otherwise structured their operations to minimize the likelihood that any pharmacy would refuse to fill suspicious orders or report suspicious practices to law enforcement. Upon information and belief, they avoided reviewing any information that might cut off high-volume dispensing practices, such as media and journal publications regarding the risks of prescribing opioids in high volumes and dosages, reports from government agencies regarding suspicious practices, questions posed by their own employees regarding suspicious practices, news reports regarding the illegal drug market and pill mills whose prescriptions they were filling, and other communications from the DEA and others regarding suspicious practices.

409. Upon information and belief, the Retailer Defendants knew that their pharmacies serving the Counties were feeding the illegal drug market. The Retailer Defendants knew about the illegal drug market. They knew which prescribers were rampantly over-prescribing opioids, including prescriptions that were plainly inappropriate. They knew that they were over-supplying New York communities with highly addictive prescription opioids at levels and in dosages that necessarily were being abused and diverted.

410. Upon information and belief, the Retailer Defendants used their market power to negotiate purchase contracts with the Distributor Defendants and/or Producer Defendants for high volumes of opioids, which in turn placed pressure on retail stores (including those serving the Counties) to meet demand and clear out the shelves regardless of whether orders were inherently

suspicious.

411. Upon information and belief, like the other defendants, they recognized that dispensing opioids at these volumes and in these dosages to New York communities necessarily was feeding and/or expanding the illegal drug market. They also knew when patients were submitting prescriptions under obviously suspicious circumstances, such as large volumes, frequently filling prescriptions for high volumes and/or high dosages, filling prescriptions for long-term supply, filling prescriptions from out-of-state or out-of-county prescribers, and filling prescription for notorious pill mill operators. They also knew when their daily prescription volumes far exceeded any conceivable medical need.

412. The DEA has investigated the Retailer Defendants for their misconduct. In 2013, CVS paid \$11 million in fines for allegations by the DEA that they violated the CSA. According to the DEA press release:

The United States has alleged that from October 6, 2005 to October 5, 2011, CVS pharmacy retail stores violated the CSA and the record-keeping regulations by:

“Creating, entering and maintaining invalid “dummy” DEA registration numbers or numbers other than the valid DEA registration number of the prescribing practitioner on dispensing records, which were at times provided to state prescription drug monitoring programs; b) Filling prescriptions for certain prescribers whose DEA registration numbers were not current or valid; and c) Entering and maintaining CVS dispensing records, including prescription vial labels, in which the DEA registration numbers of non-prescribing practitioners were substituted for the DEA registration numbers of the prescribing practitioners.”

413. Similarly, Rite Aid, as part of a multi-jurisdictional investigation by the DOJ was fined \$5 million in penalties for violating the Controlled Substances Act (“CSA”). The investigation showed that from 2004 forward, Rite Aid pharmacies across the country knowingly filled prescriptions for controlled substances that were not issued for a medically legitimate

purpose, failed to notify the DEA in a timely manner about thefts and losses of controlled substances, and/or failed to maintain or to furnish to the DEA upon request records that the CSA required to be kept in the ordinary course of business. Rite Aid also agreed to enter into a compliance plan with the DEA to ensure that it implemented an effective monitoring programs to prevent diversion. The investigation showed that Rite Aid's conduct had led to the diversion of opioids in communities across the country.

414. The Retailer Defendants have abandoned their duties imposed under federal and state law, taken advantage of a lack of DEA law enforcement, and allowed diversion in New York and Rockland County for their economic benefit.

VII. New York and Rockland County are flooded with prescription opioids, resulting in a surge in opioid overdose deaths and significant collateral damage

415. Nearly *28,000,000 opioid drug prescriptions* were dispensed in New York in 2016 alone.²⁸⁴ That is *468 prescriptions per 1,000 people*.²⁸⁵

416. New York also saw a record high 3,224 opioid-related overdose deaths in 2017,²⁸⁶ which equates to nearly nine overdose deaths every single day.

417. Between 2007 and 2016, opioid overdose deaths increased in New York by 192.4%.²⁸⁷

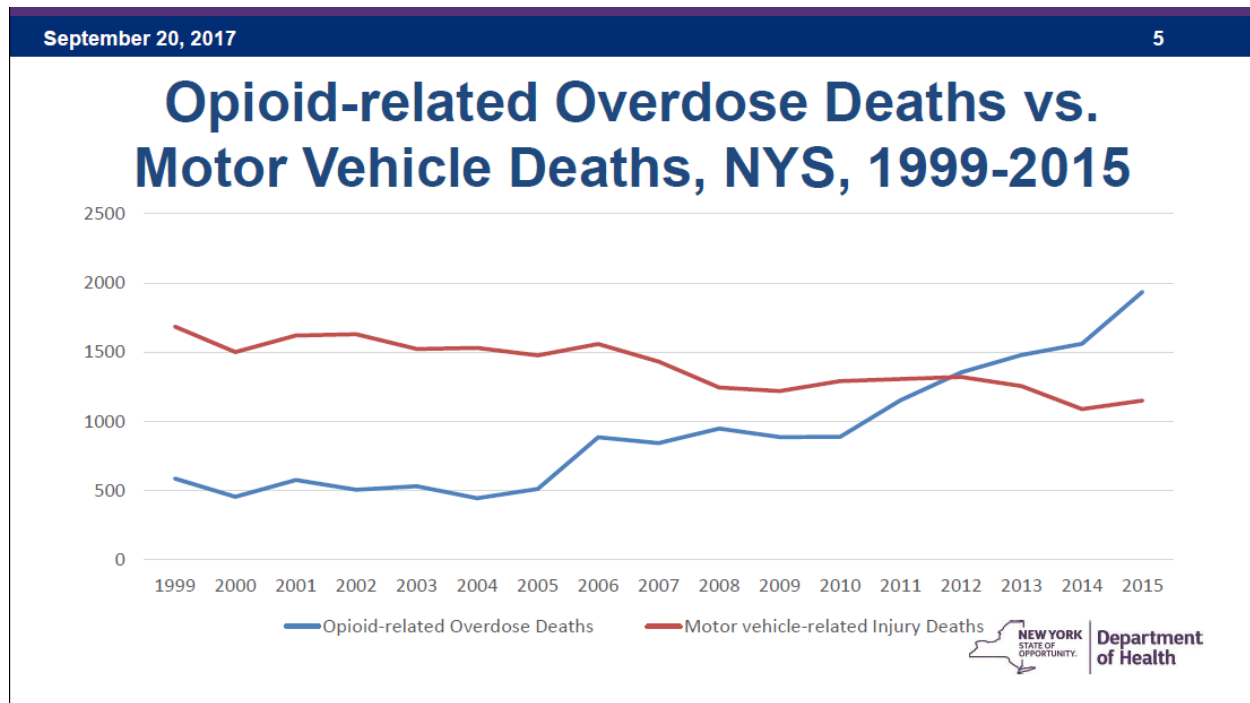
²⁸⁴ James T. Mulder, *Popping: Painkillers in NY: See Counties Prescribing the Most Opioid Drugs*, New York Upstate, available at: https://www.newyorkupstate.com/news/2018/03/new_york_state_of_painkillers_see_counties_prescribing_the_most_opioid_drugs.html.

²⁸⁵ *Id.*

²⁸⁶ New York Opioid Summary. Available at: <https://www.drugabuse.gov/opioid-summaries-by-state/new-york-opioid-summary>

²⁸⁷ N.Y. State Office of Alcoholism and Substance Abuse Services (OASAS), *New York State Epidemiological Profile: Substance Abuse and Other Mental, Emotional, and Behavioral (MEB) Disorders* (Nov. 2018) available at: https://www.oasas.ny.gov/prevention/documents/NYS_Epidemiological_Profile_12_18.pdf.

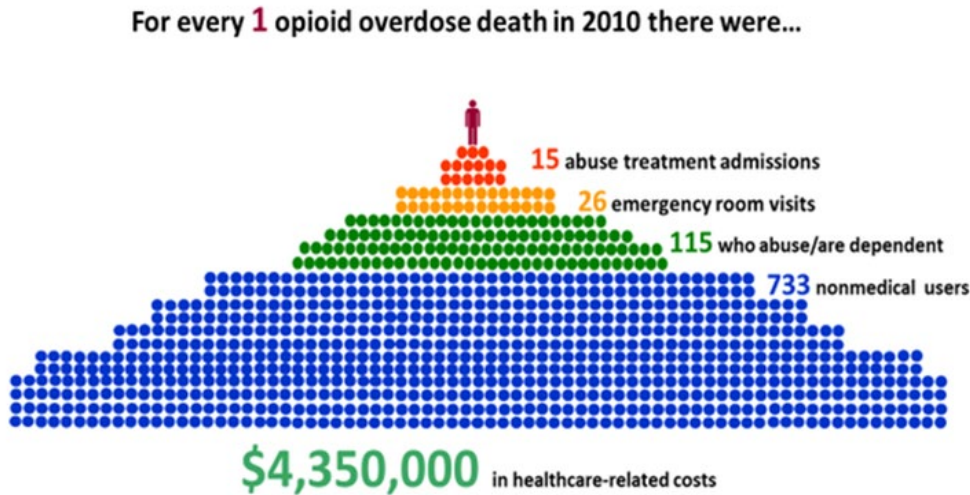
418. From 1999 through 2015, opioid related overdose deaths became exponentially more common than motor vehicle deaths:²⁸⁸



419. Opioid overdose deaths represent the “tip of the iceberg” of the human and societal costs of the opioid epidemic:²⁸⁹

²⁸⁸ *Addressing the Opioid Epidemic*, NEW YORK STATE DEPARTMENT OF HEALTH, available at: [http://www.nysac.org/files/NYSAC%20Presentation%20Opioids%20\(002\).pdf](http://www.nysac.org/files/NYSAC%20Presentation%20Opioids%20(002).pdf).

²⁸⁹ Benjamin Schachtman, ‘Closer to Home’ – The Cost of the Opioid Epidemic May be the Tip of the Iceberg, portcitydaily.com, Apr. 3, 2017 (attributing graphic chart to the N.C. Public Health Department). Available at: <http://portcitydaily.com/2017/04/03/closer-to-home-the-cost-of-the-opioid-epidemic-may-be-the-tip-of-the-iceberg/>.



420. In Rockland County, which has a population of only 328,868, there were approximately **114,874 opioid prescriptions** written in 2016 alone.²⁹⁰

421. From 2012 to 2017, Rockland County lost 146 lives to the opioid epidemic.²⁹¹ In 2016 alone, there were 36 nonfatal opioid overdose outpatient visits in Rockland County hospitals.²⁹²

422. On information and belief, tens of thousands of Rockland County residents have been or are currently addicted to opioids that were produced, shipped and sold by Defendants.

423. On information and belief, thousands of crimes committed in Rockland County involved the use, sale, or theft of opioids.

424. The opioid epidemic is so prevalent in Rockland County that Senate Minority

²⁹⁰ James T. Mulder, *Popping: Painkillers in NY: See Counties Prescribing the Most Opioid Drugs*, New York Upstate, available at: https://www.newyorkupstate.com/news/2018/03/new_york_state_of_painkillers_see_counties_prescribing_the_most_opioid_drugs.html.

²⁹¹ David Robinson, *How Rockland County Plans to Sever Links Between Opioid Prescriptions and the Morgue*, LOHUD (Jun. 6, 2018 at 12:05 PM).

²⁹² New York State – County Opioid Quarterly Report (January 2018). Available at: https://www.lihealthcollab.org/filesimages/OpiodQReport_jan18.pdf.

Leader Chuck Schumer released a press release on February 19, 2019 which highlights that the “Opioid Epidemic continues to plague Rockland Count[y], with opioid related deaths jumping...61% between ’13 and ’16.”²⁹³ Senator Schumer states that “in 2017, there were 33 overdose deaths in Rockland County 71 outpatient emergency department visits, and 650 people admitted into chemical dependence treatment programs.”²⁹⁴ Senator Schumer further states that Rockland County “hold[s] High Intensity Drug Trafficking Area (HIDTA) designation[] and routinely ha[s] some of the highest rates of opioid-related deaths in New York State.”²⁹⁵

A. New York’s epidemic of Neonatal Abstinence Syndrome (“NAS”) – a condition suffered by babies of mothers addicted to opioids

425. NAS is a clinical diagnosis, and “a consequence of the abrupt discontinuation of chronic fetal exposure to substances that were used or abused by the mother during pregnancy.”²⁹⁶

426. As illustrated by the following map, researchers analyzing hospital discharge data have determined that New York, along with its New England border states, have among the highest rates of NAS births in the nation.²⁹⁷

²⁹³ Available at: https://www.schumer.senate.gov/newsroom/press-releases/as-the-opioid-epidemic-continues-to-plague-westchester-and-rockland-counties-with-opioid-related-deaths-jumping-75_61-respectively-between-13-and-16-schumer-pushes-for-cutting-edge-technology-to-aid-westchester--rockland-police-departments-in-quickly--effectively-identifying-lethal-drugs-like-fentanyl-senator-says-congress-should-immediately-pass-new-bipartisan-grant-program-to-help-local-pds-pay-for-high-tech-tool--

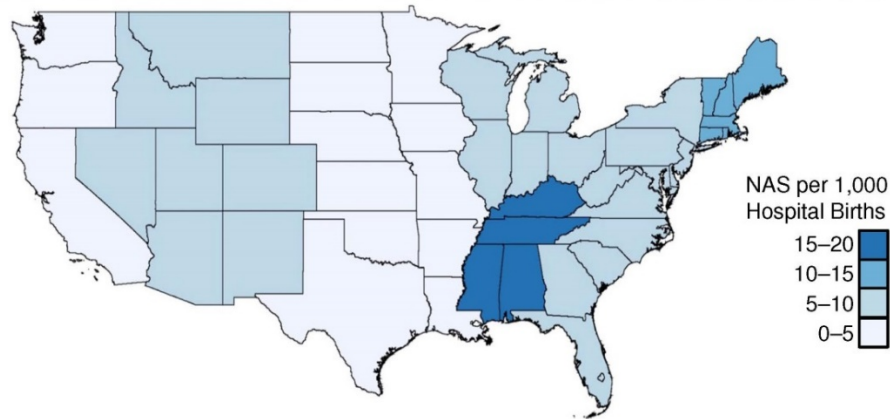
²⁹⁴ *Id.*

²⁹⁵ *Id.*

²⁹⁶ Prabhakar Kocherlakota, *Neonatal Abstinence Syndrome*, 134(2) *Pediatrics* 547, 547-48 (2014), available at <http://pediatrics.aappublications.org/content/pediatrics/134/2/e547.full.pdf>.

²⁹⁷ Stephen W. Patrick et al., *Increasing Incidence of Neonatal Abstinence Syndrome: United States 2009-2012*, 35(8) *J. Perinatol.* 650, 650-55.

NAS Incidence by Geographic Region, 2012



Patrick SW, Davis MM, Lehmann CU, et al. *J Perinatol.* 2015 Aug;35(8):650-5.

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427. NAS births in New York **increased by 350%** from 2005 to 2014.²⁹⁸ Likewise, Rockland County saw an increase in NAS births.

428. Because of the Defendants' conduct, County of Rockland has been forced to expend significant resources to respond to the opioid crisis. The damages that has been done, will likely take decades to resolve.

TOLLING AND FRAUDULENT CONCEALMENT

429. Plaintiff County of Rockland continues to suffer harm from the unlawful actions by the Defendants.

430. The continued tortious and unlawful conduct by the Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The harm is not completed nor have all the damages been

²⁹⁸ P Kocherlakota, MD, *Neonatal Abstinence Syndrome*, NEW YORK STATE PERINATAL ASSOCIATION, available at: <http://www.nysperinatal.org/resources/Pictures/Thursday%20Plenary%20-%20Neonatal%20Abstinence%20Syndrome%20-%20P.%20Kocherlakota,%20MD.pdf>

incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The public nuisance remains unabated.

431. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently assured the public, including New York and Rockland County, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status in the State and to continue generating profits. The Defendants affirmatively assured the public, including New York and Rockland County, that they were working to curb the opioid epidemic.

432. The Distributor Defendants not only acknowledged that they understood their obligations under the law, but they further publicly affirmed that their conduct was in compliance with those obligations.

433. The Distributor Defendants have also concealed and prevented discovery of information that will confirm the extent of their wrongful and illegal activities.

434. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Manufacturer Defendants invented the term “pseudoaddiction” and promoted it to an unsuspecting medical community. Manufacturer Defendants provided the medical community with false and misleading information about ineffectual medical strategies to avoid or control opioid addiction. Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids’ alleged benefits, disguising the risks, and promoting sales. The medical community, consumers, New York, and County of

Rockland were duped by the Manufacturer Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in the State and in Rockland County.

435. Plaintiff County of Rockland reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

436. Plaintiff County of Rockland's claims are equitably tolled because Defendants knowingly and fraudulently concealed the facts and their wrongful acts, and the material information pertinent to their discovery, which Defendants concealed them from the Plaintiff. Plaintiff County of Rockland did not know or could not have known through the exercise of reasonable diligence, of its claims, as a result of Defendants' conduct.

437. The purposes of the statutes of limitations period are satisfied because Defendants cannot claim prejudice due to a late filing where Plaintiff County of Rockland filed suit promptly upon discovering the facts essential to its claims, described herein, which Defendants knowingly concealed.

438. In light of their statements to the media, in legal filings, and settlements, Defendants had actual and constructive knowledge that their conduct was deceptive, in that they consciously concealed the schemes set forth herein.

439. Defendants continually and secretly engaged in their scheme to avoid compliance with their legal obligations. Only Defendants and their agents knew or could have known about Defendants' unlawful actions because Defendants made deliberate efforts to conceal their conduct. As a result of the above, Plaintiff County of Rockland was unable to obtain vital information bearing on its claims absent any fault or lack of diligence on their part.

CAUSES OF ACTION

**COUNT I:
PUBLIC NUISANCE
(New York Common Law)**

440. Plaintiff incorporates all preceding and subsequent paragraphs by reference.

441. Residents of the State of New York enjoy common rights, including, without limitation: (i) an honest and effective marketplace for healthcare treatment; (ii) the maintenance of a well-regulated system for the manufacture, distribution, and sale of controlled substances for medically-necessary purposes; (iii) public safety and public order, unburdened by the introduction of foreseeable dangers such as those caused by the over-prescription and over supply of controlled substances.

442. The public nuisance complained of herein includes the over-saturation, unlawful availability, and abuse of opioids in Rockland County for non-medical purposes, as well as the adverse social and environmental outcomes associated with widespread illegal opioid use.

443. Defendants manufactured, sold, promoted, and/or distributed prescription opioids in a manner that created, or participated in creating, a public nuisance that is harmful and injurious to Plaintiff County of Rockland and its residents.

444. The Manufacturer Defendants knew or should have known that their promotion of opioid use would create a public nuisance:

- The Manufacturer Defendants have engaged in massive production, promotion, and distribution of opioids for use by the residents of Rockland County;
- The Manufacturer Defendants' actions created and expanded the market for opioids, promoting its wide use for pain management;

- The Manufacturer Defendants misrepresented the benefits of opioids for chronic pain and fraudulently concealed, misrepresented, and omitted the serious adverse effects of opioids, including the addictive nature of the drug; and
- The Manufacturer Defendants knew or should have known that their promotion would lead to addiction and other adverse consequences and that the larger community would suffer as a result.

445. The Manufacturer Defendants' actions were a substantial factor in opioids becoming widely available and widely used. The Manufacturer Defendants' actions were a substantial factor in doctors and patients not accurately assessing and weighing the risks and benefits of opioids for chronic pain.

446. The Distributor Defendants each breached their duty to report and stop suspicious orders of prescription opioids.

447. The Retailer Defendants each breach their duty to report and stop suspicious orders of prescription opioids.

448. Without the Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted.

449. Defendants' nuisance-causing activities include illegally selling, or facilitating the illegal sale of, prescription opioids from premises in and around Rockland County to unintended users in Rockland County – including people at risk of overdose and criminals.

450. Defendants' nuisance-causing activities also include failing to implement effective controls and procedures in their supply chains to guard against theft, diversion and misuse of

prescription opioids, and their failure to adequately design and operate a system to detect, halt, and report suspicious orders of prescription opioids.

451. Defendants knowingly, intentionally, recklessly, and/or negligently disseminated massive quantities of prescription opioids to suspect physicians and pharmacies and into the black market, including pill mills and other dealers.

452. Defendants also enabled and/or failed to prevent the illegal diversion of prescription opioids into the black market, with actual knowledge, intent, and/or reckless or negligent disregard that such opioids would be illegally trafficked and abused.

453. The public nuisance created by Defendants endangers the health and safety of Rockland County and its residents.

454. The public nuisance created by Defendants has caused, and continues to cause, significant harm to County of Rockland including, but not limited to:

- The staggering rates of opioid use among adults in Rockland County has led to unnecessary opioid abuse, addiction, injuries, overdose, and deaths. It has also resulted in increased crime and property damage in Rockland County;
- Infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts;
- The Manufacturer Defendants' success in extending the market for opioids to new patients and chronic conditions has also created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury. The Manufacturer Defendants' scheme created a new secondary market for opioids – providing both the supply of narcotics to sell and the

demand of addicts to buy them;

- The diversion of opioids into the secondary, criminal market by Defendants and the increase in the number of individuals who abuse or are addicted to opioids has placed unnecessary and excessive demands on the medical, public health, law enforcement, and financial resources of County of Rockland; and
- Adults and children in Rockland County who have never taken opioids have also suffered the costs of the Defendants' public nuisance. Many have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.

455. Public resources are being unreasonably consumed in efforts to address the opioid epidemic, thereby eliminating available resources which could be used to benefit the public at large in Rockland County.

456. Defendants' nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimate societal interest in Defendants failing to identify, halt, and report suspicious opioid transactions. There is no legitimate societal interest in the Manufacturer Defendants' dissemination of false "scientific" facts and advice.

457. At all times relevant, Defendants possessed the right and ability to control the nuisance-causing outflow of prescription opioids to pharmacy locations and other points of sale into the surrounding Rockland County. Defendants had the power to shut off the supply of illicit

opioids into Rockland County. The Manufacturer Defendants had the power to stop providing false information to the market about the dangers of opioids and the highly addictive nature of their opioid products. As a direct and proximate result of the public nuisance, Rockland County has sustained harm by spending a substantial amount of money trying to fix the societal harms caused by the Defendants' nuisance-causing activity, including, but not limited to, costs of hospital services, healthcare, child services, and law enforcement.

458. Defendants should be required to pay the expenses Plaintiff County of Rockland has incurred or will incur in the future to fully abate the nuisance.

**COUNT II:
RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ("RICO")
(18 U.S.C. § 1961, *et seq.*)**

459. Plaintiff incorporates all preceding and subsequent paragraphs by reference.

460. The Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise or a legal entity enterprise. At all relevant times, the Defendants were "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

461. Section 1962(c) of RICO makes it unlawful "for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt." 18 U.S.C. § 1962(c); *United State v. Turkette*, 452 U.S. 576, 580 (1981).

462. The term "enterprise" includes "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although

not a legal entity.” 18 U.S.C. § 1961(4); *Turkette*, 452 U.S. at 580; *Boyle v. United States*, 556 U.S. 938, 944 (2009); *United Food & Commercial Workers Unions & Employers Midwest Health Benefits Fund v. Walgreen Co.*, 719 F.3d 849, 853 (7th Cir. 2013). The definition of “enterprise” in Section 1961(4) includes both legitimate and illegitimate enterprises. Specifically, the section “describes two separate categories of associations that come within the purview of an ‘enterprise’ – the first encompassing organizations such as corporations, partnerships, and other ‘legal entities,’ and the second covering ‘any union or group of individuals associated in fact although not a legal entity.’” *Turkette*, 452 U.S. at 577. The second category is not a more generalized description of the first. *Id.*

463. For over a decade, the Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, the Defendants are not permitted to engage in a limitless expansion of their market through the unlawful sales of regulated painkillers. As “registrants,” the Defendants operated and continue to operate within the “closed-system” created under the Controlled Substances Act, 21 U.S.C. § 821, *et seq.* (the “CSA”). The CSA restricts the Defendants’ ability to manufacture or distribute Schedule II substances like opioids by requiring them to: (1) register to manufacture or distribute opioids; (2) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute; (3) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA; and (4) make sales within a limited quota set by the DEA for the overall production of Schedule II substances like opioids.

464. The closed-system created by the CSA, including the establishment of quotas, was specifically intended to reduce or eliminate the diversion of Schedule II substances like opioids

from “legitimate channels of trade” to the illicit market “by controlling the quantities of the basic ingredients needed for the manufacture of [controlled substances].”²⁹⁹

465. Defendants’ illegal scheme was implemented by an association-in-fact enterprise between the Manufacturer Defendants and the Distributor Defendants, and executed by each of them. In particular, each of the Defendants was associated with, and conducted or participated in, the affairs of the RICO enterprise, whose purpose was to engage in the unlawful sales of opioids, deceive the public and federal and state regulators into believing that the Defendants were faithfully fulfilling their statutory obligations. The Defendants’ scheme allowed them to make billions in unlawful sales of opioids and, in turn, increase and maintain high production quotas with the purpose of ensuring unlawfully increasing revenues, profits, and market share. As a direct result of the Defendants’ fraudulent scheme, course of conduct, and pattern of racketeering activity, they were able to extract billions of dollars of revenue, while County of Rockland suffered injury caused by the reasonably foreseeable consequences of the opioid epidemic. As explained in detail below, the Defendants’ misconduct violated Section 1962(c) and Plaintiff is entitled to treble damages for their injuries under 18 U.S.C. § 1964(c).

466. Alternatively, the Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which the Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States. Specifically, the Healthcare Distribution Alliance (the “HDA”)³⁰⁰ is a distinct legal entity that satisfies the

²⁹⁹ 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, *Drugcaucus.senate.gov*, U.S. Dept. of Justice, Drug Enforcement Administration, Before the Caucus on International Narcotics Control, United States Senate, 5 May 2015. (Hereinafter “Rannazzisi May 5, 2015 Testimony”).

³⁰⁰ Health Distribution Alliance, *History*, Health Distribution Alliance, <https://www.healthcaredistribution.org/about/hda-history>.

definition of a RICO enterprise. The HDA is a non-profit corporation formed under the laws of the District of Columbia and doing business in Virginia. As a non-profit corporation, HDA qualifies as an “enterprise” within the definition set out in 18 U.S.C. § 1961(4) because it is a corporation and a legal entity. The Defendants are members, participants, and/or sponsors of the HDA and utilized the HDA to conduct the Opioid Diversion Enterprise and to engage in the pattern of racketeering activity that gives rise to the Count.

467. Each of the Defendants is a legal entity separate and distinct from the HDA. Further, the HDA serves the interests of distributors and manufacturers beyond the Defendants. Therefore, the HDA exists separately from the Opioid Diversion Enterprise, and each of the Defendants exists separately from the HDA. Therefore, the HDA itself serves as a RICO enterprise.

468. The legal and association-in-fact enterprises were each used by the Defendants to conduct the Opioid Diversion Enterprise by engaging in a pattern of racketeering activity. Therefore, the legal and association-in-fact enterprises are plead in the alternative and are collectively referred to as the “Opioid Diversion Enterprise.”

469. **The Opioid Diversion Enterprise:** In 2006 and 2007, the DEA issued multiple letters to the Distributor Defendants reminding them of their obligation to maintain effective controls against diversion of particular controlled substances, to design and operate a system to disclose suspicious orders, and to inform the DEA of any suspicious orders.³⁰¹ The DEA also published suggested questions that a distributor should ask prior to shipping controlled substances in order to know their customers.³⁰²

³⁰¹ Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (Sept. 27, 2006); Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (Dec. 27, 2007).

³⁰² See “Suggested Questions a Distributor should ask prior to Shipping Controlled

470. Central to the closed-system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from “legitimate channels of trade” by controlling the “quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs.”³⁰³

471. When evaluating production quotas, the DEA was instructed to consider the following information:

- Information provided by the Department of Health and Human Services;
- Total net disposal of the basic class by all manufacturers;
- Trends in the national rate of disposal of the basic class;
- An applicant’s production cycle and current inventory position;
- Total actual or estimated inventories of the class and of all substances manufactured from the class and trends in inventory accumulation; and
- Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies.³⁰⁴

472. It is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.³⁰⁵

Substances, *Deadiversion.usdoj.gov*/, U.S. Dept. of Justice, Drug Enforcement Administration.

³⁰³ 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Rannazzisi May 5, 2015 Testimony.

³⁰⁴ Rannazzisi May 5, 2015 Testimony at 3.

³⁰⁵ *Id.* at 4 (citing 21 U.S.C. § 842(b)).

473. At all relevant times, the Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues, and profits by disregarding their statutory duty to identify, investigate, halt, and report suspicious orders of opioids and diversion of their drugs into the illicit market, in order to unlawfully increase the quotas set by the DEA and allow them to collectively benefit from the unlawful formation of a greater pool of prescription opioids from which to profit. The Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

474. At all relevant times, the Opioid Diversion Enterprise: (a) had an existence separate and distinct from each Defendant; (b) was separate and distinct from the pattern of racketeering in which the Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the Defendants; (d) characterized by interpersonal relationships among the Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. *Turkette*, 452 U.S. at 580; *Boyle*, 556 U.S. at 944. Each member of the Opioid Diversion Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid sales generated as a result of the Opioid Diversion Enterprise's disregard for their duty to prevent diversion of their drugs into the illicit market and then requesting the DEA increase production quotas, all so that the Defendants would have a larger pool of prescription opioids from which to profit.

475. The Opioid Diversion Enterprise also engaged in efforts to lobby against the DEA's authority to hold the Defendants liable for disregarding their duty to prevent diversion. Members of the Pain Care Forum ("PCF"), described in greater detail below, and the HDA lobbied for the passage of legislation to weaken the DEA's enforcement authority. The Ensuring Patient Access

and Effective Drug Enforcement Act significantly reduced the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations.³⁰⁶ The HDA and other members of the PCF contributed substantial amounts of money to political campaigns for federal candidates, state candidates, political action committees, and political parties. The PCF and its members spent significant funds on lobbying efforts while the HDA devoted over a million dollars a year to its lobbying efforts between 2011 and 2016.

476. The Opioid Diversion Enterprise functioned by selling prescription opioids. While there are some legitimate uses and/or needs for prescription opioids, the Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity, that involves a fraudulent scheme to increase revenue by violating State and Federal laws requiring the maintenance of effective controls against diversion of prescription opioids, and the identification, investigation, and reporting of suspicious orders of prescription opioids destined for the illicit drug market. The goal of Defendants' scheme was to increase profits from opioid sales. But, Defendants' profits were limited by the production quotas set by the DEA, so the Defendants refused to identify, investigate, and/or report suspicious orders of their prescription opioids being diverted into the illicit drug market. The end result of this strategy was to increase and maintain artificially high production quotas of opioids so that there was a larger pool of opioids for Defendants to manufacture and distribute for public consumption.

477. The Opioid Diversion Enterprise engaged in, and its activities affected, interstate

³⁰⁶ See "HDMA is now the Healthcare Distribution Alliance," *Pharmaceuticalcommerce.com*, 13 June 2016, updated 6 July 2016.; Bernstein, Lenny et al, "Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control," *The Washington Post*, 22 Oct. 2016.; Higham, Scott et al., "U.S. Senator Calls for Investigation of DEA Enforcement Slowdown amid Opioid Crisis," *The Washington Post*, 6 Mar. 2017.; Eyre, Eric, "DEA Agent: 'We Had no Leadership' in West Virginia Amid Flood of Pain Pills," *100daysinappalachia.com/*.

and foreign commerce because the enterprise involved commercial activities across states lines, such as manufacture, sale, distribution, and shipment of prescription opioids throughout Rockland County and this jurisdiction, and the corresponding payment and/or receipt of money from the sale of the same.

478. Within the Opioid Diversion Enterprise, there were interpersonal relationships and common communication by which the Defendants shared information on a regular basis. These interpersonal relationships also formed the organization of the Opioid Diversion Enterprise. The Opioid Diversion Enterprise used their interpersonal relationships and communication network for the purpose of conducting the enterprise through a pattern of racketeering activity.

479. Each of the Defendants had a systematic link to each other through joint participation in lobbying groups, trade industry organizations, contractual relationships, and continuing coordination of activities. The Defendants participated in the operation and management of the Opioid Diversion Enterprise by directing its affairs, as described herein. While the Defendants participated in, and are members of, the enterprise, they each have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

480. The Defendants exerted substantial control over the Opioid Diversion Enterprise by their membership in the PCF, the HDA, and through their contractual relationships.

481. The PCF has been described as a coalition of drug makers, trade groups, and dozens of non-profit organizations supported by industry funding. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

482. The Center for Public Integrity and the Associated Press obtained “internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse.”³⁰⁷ Specifically, PCF participants spent over \$740 million lobbying in the nation’s capital and in all 50 state houses on an array of issues, including opioid-related measures.”³⁰⁸

483. Not surprisingly, each of the Defendants who stood to profit from lobbying in favor of prescription opioid use is a member of and/or participant in the PCF.³⁰⁹ In 2012, membership and participating organizations included the HDA (of which all Defendants are members), Purdue, Janssen, and Cephalon.³¹⁰ Each of the Manufacturer Defendants worked together through the PCF to advance the interests of the enterprise. But, the Manufacturer Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.³¹¹

484. The 2012 PCF Meeting Schedule demonstrates that each of the Defendants participated in meetings on a monthly basis, either directly or through their trade organization, in a coalition of drug makers and their allies whose sole purpose was to shape the national response to the ongoing prescription opioid epidemic, including the concerted lobbying efforts that the PCF undertook on behalf of its members.

485. Second, the HDA led to the formation of interpersonal relationships and an

³⁰⁷ Perrone, Matthew, “Pro-Painkiller Echo Chamber Shaped Policy Amid Drug Epidemic,” *The Center for Public Integrity*, 19 Sept. 2016, updated 15 Dec. 2016.

³⁰⁸ *Id.*

³⁰⁹ PAIN CARE FORUM 2012 Meetings Schedule, <https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Scheduleamp.pdf>, last updated Dec. 2011.

³¹⁰ *Id.*

³¹¹ *Id.*

organization between the Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Manufacturer Defendants are members.³¹² And, the HDA and each of the Distributor Defendants sought the active membership and participation of the Manufacturer Defendants by advocating that one of the benefits of membership included the ability to develop direct relationships between Manufacturers and Distributors at high executive levels.

486. In fact, the HDA touted the benefits of membership to the Manufacturer Defendants, advocating that membership included the ability to, among other things, “network one on one with manufacturer executives at HDA’s members-only Business and Leadership Conference,” “networking with HDA wholesale distributor members,” “opportunities to host and sponsor HDA Board of Directors events,” “participate on HDA committees, task forces and working groups with peers and trading partners,” and “make connections.”³¹³ The HDA and the Distributor Defendants used membership in the HDA as an opportunity to create interpersonal and ongoing organizational relationships between the Manufacturer and Distributor Defendants.

487. The application for manufacturer membership in the HDA further indicates the level of connection that existed between the Defendants.³¹⁴ The manufacturer membership application must be signed by a “senior company executive,” and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company. The HDA application also requests that the manufacturer identify its current distribution information and its

³¹² “Manufacturer Membership,” *Healthcaredistribution.org*, Healthcare Distribution Alliance.

³¹³ “Manufacturer Membership Benefits,” *Healthcaredistribution.org*, Healthcare Distribution Alliance.

³¹⁴ “Manufacturer Membership Application Instructions,” *Healthcaredistribution.org*, Healthcare Distribution Alliance. Web

most recent year-end net sales through any HDA distributors, including but not limited to: Defendants AmerisourceBergen, Cardinal Health, and McKesson.

488. After becoming members, the Distributors and Manufacturers were eligible to participate on councils, committees, task forces and working groups, which promoted the Opioid Diversion Enterprise efforts, including lobbying and even development of chargebacks.³¹⁵

489. The councils, committees, task forces and working groups provided the Manufacturer and Distributor Defendants with the opportunity to work closely together in shaping their common goals and forming the enterprise's organization.

490. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the Manufacturer Defendants as an opportunity to "bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues."³¹⁶ The conferences also gave the Manufacturer and Distributor Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry."³¹⁷ The HDA and its conferences were significant opportunities for the Manufacturer and Distributor Defendants to interact at a high-level of leadership. And, it is clear that the Manufacturer Defendants embraced this opportunity by attending and sponsoring these events.³¹⁸

491. Third, the Defendants maintained their interpersonal relationships by working

³¹⁵ "Councils and Committees," *Healthcaredistribution.org*, Healthcare Distribution Alliance.

³¹⁶ "Business and Leadership Conference – Information for Manufacturers," *Healthcaredistribution.org*, Healthcare Distribution Alliance.

³¹⁷ *Id.*

³¹⁸ See "2015 Distribution Management Conference and Expo," Healthcare Distribution Alliance, *Healthcaredistribution.org*, Healthcare Distribution Alliance.

together and exchanging information and driving the unlawful sales of their opioids through their contractual relationships, including chargebacks and vault security programs.

492. The Manufacturer Defendants engaged in an industry-wide practice of paying rebates and chargebacks to the Distributor Defendants for sales of prescription opioids. As reported in the Washington Post, identified by Senator McCaskill, and acknowledged by the HDA, there is an industry-wide practice whereby the Manufacturer Defendants paid the Distributor Defendants rebates and/or chargebacks on their prescription opioid sales. These contracts were negotiated at the highest levels, demonstrating ongoing relationships between the Manufacturer and Distributor Defendants. In return for the rebates and chargebacks, the Distributor Defendants provided the Manufacturer Defendants with detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices.³¹⁹ The Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell the prescription opioids.

493. The contractual relationships among the Defendants also include vault security programs. The Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opioids. Manufacturers likely negotiated agreements whereby the Manufacturers installed security vaults for Distributors in exchange for agreements to maintain minimum sales performance thresholds. These agreements were used by the Defendants as a tool to violate their reporting and anti-diversion duties.

494. Taken together, the interaction and length of the relationships between and among

³¹⁹ See “Webinar Leveraging EDI: Order-to-Cash Transactions CD Box Set,” *Healthcaredistribution.org*, Healthcare Distribution Alliance.

the Manufacturer and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. The Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids. The HDA and the PCF are but two examples of the overlapping relationships and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the Defendants were in communication and cooperation.

495. According to articles published by the Center for Public Integrity and The Associated Press, the PCF has been lobbying on behalf of the Manufacturer and Distributor Defendants for “more than a decade.”³²⁰ Similarly, the HDA has continued its work on behalf of Defendants, without interruption, since at least 2000, if not longer.³²¹

496. As described above, the Defendants began working together as early as 2006 through the PCF and the HDA to promote the common purpose of their enterprise. Defendants worked together as an ongoing and continuous organization throughout the existence of their enterprise.

497. **Conduct of the Opioid Diversion Enterprise:** During the time period alleged in this complaint, the Defendants exerted control over, conducted and/or participated in the Opioid Diversion enterprise by fraudulently failing to comply with their Federal and State obligations to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, to halt such unlawful sales and, in doing so, to increase production quotas and generate unlawful profits.

³²⁰ Perrone, Matthew, “Pro-Painkiller Echo Chamber Shaped Policy Amid Drug Epidemic,” *The Center for Public Integrity*, 19 Sept. 2016, updated 15 Dec. 2016.

³²¹ “History,” *Healthcaredistribution.org*, Healthcare Distribution Alliance.

498. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to maintain effective controls against diversion of their prescription opioids.

499. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids.

500. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids.

501. Defendants paid nearly \$800 million dollars to influence local, state, and federal governments through joint lobbying efforts as part of the PCF. The Defendants were all members of the PCF either directly or indirectly through the HDA. The lobbying efforts of the PCF and its members included efforts to pass legislation making it more difficult for the DEA to suspend and/or revoke the Manufacturers' and Distributors' registrations for failure to report suspicious orders of opioids.

502. The Defendants exercised control and influence over the distribution industry by participating and maintaining membership in the HDA.

503. The Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."

504. The Defendants engaged in an industry-wide practice of paying rebates and chargebacks to incentivize unlawful opioid prescription sales. The Manufacturer Defendants used

the chargeback program to acquire detailed, high-level data regarding sales of the opioids they manufactured. The Manufacturer Defendants also used this high-level information to direct the Distributor Defendants' sales efforts to regions where prescription opioids were selling in larger volumes.

505. The Manufacturer Defendants lobbied the DEA to increase Aggregate Production Quotas year after year by submitting net disposal information that the Manufacturer Defendants knew included sales that were suspicious and involved the diversion of opioids that had not been properly investigated or reported by the Defendants.

506. The Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007, was intended to help the Defendants identify suspicious orders or customers who were likely to divert prescription opioids.³²² The "know your customer" questionnaires informed the Defendants of the number of pills that the pharmacies sold, how many non-controlled substances are sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area including pain clinics, general practitioners, hospice facilities, and cancer treatment facilities, and these questionnaires also put the recipients on notice of suspicious orders.

507. The Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of them despite their actual knowledge of drug diversion rings. The Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012 and 117 recommended decisions in registrant actions from The Office of Administrative Law Judges.

³²² See Widup, Richard et al., "*Pharmaceutical Production Diversion: Beyond the PDMA*," *Mcguirewoods.com*.

These numbers include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders – all for failure to report suspicious orders.

508. The Defendants' scheme had decision-making structure that was driven by the Manufacturer Defendants and corroborated by the Distributor Defendants. The Manufacturer Defendants worked together to control the state and federal governments' response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion, and to identify and report suspicious orders to the DEA.

509. The Defendants worked together to control the flow of information and influence state and federal governments and politicians to pass legislation that benefitted Defendants. The Manufacturer and Distributor Defendants did this through their participation in the PCF and HDA.

510. The Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas, and Procurement Quotas allowed by the DEA stayed high and ensured that suspicious orders were not reported to the DEA. By not reporting suspicious orders or diversion of prescription opioids, the Defendants ensured that the DEA had no basis for decreasing or refusing to increase the production quotas for prescription opioids due to diversion of suspicious orders. The Defendants influenced the DEA production quotas in the following ways:

- The Distributor Defendants assisted the enterprise and the Manufacturer Defendants in their lobbying efforts through the PCF;
- The Distributor Defendants invited the participation, oversight and control of the Manufacturer Defendants by including them in the HDA, including on the councils, committees, task forces, and working groups;
- The Distributor Defendants provided sales information to the Manufacturer

Defendants regarding their prescription opioids, including reports of all opioids prescriptions filled by the Distributor Defendants;

- The Manufacturer Defendants used a chargeback program to ensure delivery of the Distributor Defendants' sales information;
- The Manufacturer Defendants obtained sales information from QuintilesIMS (formerly IMS Health) that gave them a "stream of data showing how individual doctors across the nation were prescribing [opioids]";
- The Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;
- The Manufacturer Defendants used the Distributor Defendants' sales information and the data from QuintilesIMS to instruct the Distributor Defendants to focus their distribution efforts to specific areas where the purchase of prescription opioids was most frequent;
- The Defendants identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market;
- The Defendants refused to report suspicious orders of prescription opioids despite repeated investigation and punishment of the Distributor Defendants by the DEA for failure to report suspicious orders; and
- The Defendants withheld information regarding suspicious orders and illicit diversion from the DEA because it would have revealed that the "medical

need” for and the net disposal of their drugs did not justify the production quotas set by the DEA.

511. The scheme devised and implemented by the Defendants amounted to a common course of conduct characterized by a refusal to maintain effective controls against diversion, and all designed and operated to ensure the continued unlawful sale of controlled substances.

512. **Pattern of Racketeering Activity:** The Defendants conducted and participated in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(B), including mail fraud (18 U.S.C. § 1341) and wire fraud (18 U.S.C. § 1343); and 18 U.S.C. § 1961(D) by the felonious manufacture, importation, receiving, concealment, buying selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

513. The Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public, including New York and Rockland County, by knowingly conducting or participating in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

514. The Defendants committed, conspired to commit, and aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a “pattern of racketeering activity.” The racketeering activity was made possible by the Defendants’ regular use of the

facilities, services, distribution channels, and employees of the Opioid Diversion Enterprise. The Defendants participated in the scheme to defraud by using mail, telephone, and the internet to transmit mailings and wires in interstate or foreign commerce.

515. The Defendants used, directed the use of, and caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments, and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

516. In devising and executing the illegal scheme, the Defendants devised and knowingly carried out a material scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts. For the purpose of executing the illegal scheme, the Defendants committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

517. The Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

- Mail Fraud: The Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.
- Wire Fraud: The Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials

by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

518. The Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Manufacturer Defendants, Distributor Defendants, or third parties that were foreseeably caused to be sent as a result of the Defendants' illegal scheme, including but not limited to:

- The prescription opioids themselves;
- Documents and communications that facilitated the manufacture, purchase and unlawful sale of prescription opioids;
- The Defendants' DEA registrations;
- Documents and communications that supported and facilitated the Defendants' DEA registrations;
- Documents and communications that supported and facilitated the Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;
- The Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;
- Documents and communications related to the Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;
- Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports, and correspondence;

- Documents for processing and receiving payment for prescription opioids;
- Payments from the Distributor Defendants to the Manufacturer Defendants;
- Rebates and chargebacks from the Manufacturer Defendants to the Distributor Defendants;
- Payments to the Defendants' lobbyists through the PCF;
- Payments to the Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;
- Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and
- Other documents and things, including electronic communications.

519. The Defendants, for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce.

520. The Defendants also used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate, and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

521. At the same time, the Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and that they complied with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

522. Defendants also utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

523. The Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

524. Several Defendants also entered into various Corporate Integrity Agreements with various entities, including the Office of Inspector General and the United States Department of Health and Human Services, that required the Defendants annually to certify in writing that the Defendants had implemented effective compliance programs and were otherwise in compliance with laws and regulations regarding, among other things, the manufacture and distribution of opioids. Defendants submitted through the mail and wires certifications that were false and misleading, in furtherance of the Opioid Diversion Enterprise's operation and goals, including false and misleading certifications required annually under the following:

- Section III of the Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Johnson & Johnson (fully executed on Oct. 31, 2013); and
- Section III of the Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Purdue Pharma, L.P. (fully executed on May 8, 2007).

525. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct to deceive regulators and the public that Defendants were complying with their state and federal obligations to identify and report

suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The Defendants' scheme and common course of conduct was intended to increase or maintain high production quotas for their prescription opioids from which they could profit.

526. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden, and cannot be alleged without access to Defendants' books and records. But, Plaintiff has described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

527. The Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. These actions violate 18 U.S.C. § 1962(c). Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with the Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the Defendants.

528. The Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

529. The Defendants hid from the general public, and suppressed and ignored warnings from third parties, whistleblowers and governmental entities, about the reality of the suspicious orders that the Defendants were filling on a daily basis—leading to the diversion of tens of millions of doses of prescriptions opioids into the illicit market.

530. The Defendants, with knowledge and intent, agreed to the overall objective of their

fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

531. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding marketing prescription opioids and refusing to report suspicious orders.

532. The Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

533. The predicate acts all had the purpose of generating significant revenue and profits for the Defendants while Plaintiff was left with substantial injury to its business and property through the damage that the prescription opioid epidemic caused. The predicate acts were committed or caused to be committed by the Defendants through their participation in the Opioid Diversion Enterprise and in furtherance of its fraudulent scheme.

534. The pattern of racketeering activity and the Opioid Diversion Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the enterprise.

535. The pattern of racketeering activity is continuing as of the date of this Complaint and will continue into the future unless enjoined by this Court.

536. Many of the precise dates of the Defendants' criminal actions have been hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Diversion Enterprise alleged herein depended upon secrecy.

537. Each instance of racketeering activity was related, had similar purposes, involved

the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers in this jurisdiction and Plaintiff. Defendants calculated and intentionally crafted the Opioid Diversion Enterprise and their scheme to increase and maintain their increased profits without regard to the effect such behavior would have on Plaintiff, its residents, and its community. In designing and implementing the scheme, at all times Defendants knew that those in the manufacturing and distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and reliable information regarding Defendants' products and their manufacture and distribution of those products. The Defendants were also aware that Plaintiff and the citizens of this jurisdiction rely on the Defendants to maintain a closed system and to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

538. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

539. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations, would harm Plaintiff by allowing the flow of prescriptions opioids from appropriate medical channels into the illicit drug market.

540. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

541. **The RICO Defendants manufactured, sold, and/or dealt in controlled substances and their crimes are punishable as felonies:** The Defendants conducted and participated in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(D) by the felonious manufacture, importation,

receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

542. The Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 483(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter. A violation of section 483(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 483(d)(1).

543. Each of the Defendants qualifies as a registrant under the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances, and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

544. Pursuant to the CSA and the Code of Federal Regulations, the RICO Defendants were required to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders.

545. The Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and omitted material information from reports, records, and other documents required to be filed with the DEA, including the Manufacturer Defendants' applications for production quotas. Specifically, the Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports

and their applications for production quotas.

546. For example, the DEA and DOJ began investigating McKesson in 2013 regarding its monitoring and reporting of suspicious controlled substances orders. On April 23, 2015, McKesson filed a Form-8-K announcing a settlement with the DEA and DOJ wherein it admitted to violating the CSA and agreed to pay \$150 million and have some of its DEA registrations suspended on a staggered basis. The settlement was finalized in January 2017.

547. Purdue's experience with the organized drug ring in Los Angeles, which Purdue knew about but failed to report to the DEA, is another striking example of Defendants' willful violation of the CSA and Code of Federal Regulations as it relates to reporting suspicious orders of prescription opioids.

548. Mallinckrodt also was recently the subject of a DEA and Senate investigation for its opioid practices. Specifically, in 2011, the DEA targeted Mallinckrodt arguing that it ignored its responsibility to report suspicious orders as 500 million of its pills ended up in Florida between 2008 and 2012. After six years of DEA investigation, Mallinckrodt agreed to a settlement involving a \$35 million fine. Federal prosecutors summarized the case by saying that Mallinckrodt's response was that everyone knew what was going on in Florida but they had no duty to report it.

549. These examples reflect the Defendants' pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74. This conclusion is supported by the sheer volume of enforcement actions available in the public record against the Distributor Defendants.

550. The pattern of racketeering activity is continuing as of the date of this Complaint and will likely continue into the future unless enjoined by this Court.

551. Many of the precise dates of Defendants' criminal actions were hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Diversion Enterprise depended upon the secrecy of the participants in that enterprise.

552. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff, its residents, and its community. Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on this jurisdiction, its citizens or the Plaintiff. The Defendants were aware that Plaintiff and the citizens of this jurisdiction rely on the Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

553. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

554. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations, would harm Plaintiff by allowing the flow of prescriptions opioids from appropriate medical channels into the illicit drug market.

555. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

556. **Damages**: The Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff's injury in its business and property because

Plaintiff paid for costs associated with the opioid epidemic.

557. Plaintiff's injuries, and those of their residents and community, were proximately caused by Defendants' racketeering activities. But for the Defendants' conduct, Plaintiff would not have paid the health services and law enforcement services and expenditures required as a result of the plague of drug-addicted residents.

558. Plaintiff's injuries and those of its residents and community were directly caused by the Defendants' racketeering activities.

559. Plaintiff was most directly harmed and there are no other plaintiffs better suited to seek a remedy for the economic harms at issue here.

560. Plaintiff seeks all legal and equitable relief as allowed by law, including actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney's fees and all costs and expenses of this lawsuit and pre- and post-judgment interest.

**COUNT III:
RICO CONSPIRACY
(18 U.S.C. § 1962(d))**

561. Plaintiff incorporates all preceding and subsequent paragraphs by reference.

562. At all relevant times, the Defendants were associated with the Opioid Diversion Enterprise and agreed and conspired to violate 18 U.S.C. § 1962(c), that is, they agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(d). Under Section 1962(d) it is unlawful for "any person to conspire to violate" Section 1962(d), among other provisions. 18 U.S.C. § 1962(d).

563. Defendants conspired to violate Section 1962(c), as alleged more fully above, by conducting the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity.

**COUNT IV:
NEGLIGENCE**

564. Plaintiff incorporates all preceding and subsequent paragraphs by reference.

565. Defendants had an obligation to use reasonable care in manufacturing, marketing, selling, and distributing highly dangerous opioid drugs to New York and Rockland County, and the injuries alleged in this Complaint from the breach of that duty were foreseeable, and in fact were foreseen, by Defendants. *See City of Everett v. Purdue Pharma L.P. et al.*, No. C17-209RSM, 2017 WL 4236062 at *4, 6-7 (W.D. Wash. Sept. 25, 2017) (sustaining a negligence claim by city against Purdue for damages caused by the opioid crisis).

566. Reasonably prudent manufacturers, distributors, and retailers of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities, and the significant costs which would be imposed upon the governmental entities associated with those communities. The closed system of opioid distribution whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies, and wherein all links in the chain have a duty to prevent diversion, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse.

567. Reasonably prudent manufacturers of pharmaceutical products would know that aggressively pushing highly addictive opioids for chronic pain would result in the severe harm of addiction, foreseeably causing patients to seek increasing levels of opioids, frequently turning to the illegal drug market as a result of a drug addiction that was foreseeable to the Manufacturer Defendants.

568. Moreover, Defendants were repeatedly warned by law enforcement of the unlawfulness and consequences of their actions and omissions.

569. The escalating amounts of addictive drugs flowing through Defendants' businesses,

and the sheer volume of these prescription opioids, further alerted Defendants that addiction was fueling increased consumption and that legitimate medical purposes were not being served.

570. Distributor Defendants breached their duties to exercise due care in the business of wholesale distribution of dangerous opioids, which are Schedule II Controlled Substances, by failing to monitor for, failing to report, and filling highly suspicious orders time and again. Because the very purpose of these duties was to prevent the resulting harm – diversion of highly addictive drugs for non- medical purposes – the causal connection between Defendants’ breach of duties and the ensuing harm was entirely foreseeable.

571. Distributor Defendants misrepresented their compliance with their duties under the law and concealed their noncompliance and shipments of suspicious orders of opioids to New York and Rockland County and destinations from which they knew opioids were likely to be diverted into New York and Rockland County, in addition to other misrepresentations alleged and incorporated herein.

572. Retailer Defendants breached their duties to exercise due care in the business of retail distribution of dangerous opioids, which are Schedule II Controlled Substances, by failing to monitor for, failing to report, and filling highly suspicious orders time and again. Because the very purpose of these duties was to prevent the resulting harm – diversion of highly addictive drugs for non- medical purposes – the causal connection between Defendants’ breach of duties and the ensuing harm was entirely foreseeable.

573. Retailer Defendants misrepresented their compliance with their duties under the law and concealed their noncompliance and filling of suspicious orders of opioids to New York and Rockland County and destinations from which they knew opioids were likely to be diverted into New York and Rockland County, in addition to other misrepresentations alleged and

incorporated herein.

574. Manufacturer Defendants breached their duties to exercise due care in the business of pharmaceutical manufacturers of dangerous opioids, which are Schedule II Controlled Substances, and by misrepresenting the nature of the drugs and aggressively promoting them for chronic pain for which they knew the drug were not safe or suitable.

575. The Manufacturer Defendants misrepresented and concealed the addictive nature of prescription opioids and its lack of suitability for chronic pain, in addition to other misrepresentations alleged and incorporated herein.

576. All Defendants breached their duties to prevent diversion and report and halt suspicious orders, and all Defendants misrepresented their compliance with their legal duties.

577. Defendants' breaches were intentional and unlawful, and Defendants' conduct was willful, wanton, malicious, reckless, oppressive, and fraudulent.

578. The causal connection between Defendants' breaches of duties and misrepresentations and the ensuing harm was entirely foreseeable.

579. Defendants' breaches of duty and misrepresentations caused, bear a causal connection with, and proximately resulted in the damages sought herein.

580. Defendants were selling dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Defendants knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than medical, scientific, or industrial channels. However, Defendants breached their duties to monitor for, report, and halt suspicious orders, breached their duties to prevent diversion, and, further, misrepresented what their duties were and their compliance with their legal duties.

581. As a direct and proximate result of Defendants' breaches of duties, Plaintiff has

been harmed and damaged.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that the Court:

- A. Enter judgment against Defendants jointly and severally and in favor of Plaintiff;
- B. Award damages in an amount sufficient to fairly and completely compensate Plaintiff for all damages;
- C. Award actual and triple the actual damages County of Rockland sustained as a result of the Defendants' RICO violations;
- D. Award pre-judgment and post-judgment interest as provided by law, and award such interest at the highest legal rate;
- E. Enter an order of abatement and permanent injunction against all Defendants prohibiting them from engaging in the unlawful conduct detailed herein, including over-promotion and over-saturation of opioids in and around Rockland County;
- F. Enter an order requiring Defendants to establish an "abatement fund" for the purpose of abating the opioid nuisances;
- G. Award Plaintiff the costs of this lawsuit, including reasonable attorneys' fees and expenses as provided by law;
- H. Award such further and additional relief as the Court may deem just and proper under the circumstances.

JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38, County of Rockland demands a jury trial on all issues so triable.

Filed on this the 14th day of June, 2019.

Respectfully submitted,

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